

# Study on the Legal Aspects of Supplementary Protection Certificates in the EU

Annex III: Survey on the Legal Aspects
of the Supplementary Protection
Certificates in the EU

The Findings of a Survey among
Stakeholders in the EU Member States (2017)



#### **EUROPEAN COMMISSION**

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs Directorate F  $\,-\,$  Innovation and Advanced Manufacturing Unit GROW-F.5  $\,-\,$  Intellectual property and Fight against Counterfeiting

Contact: Alfonso CALLES SANCHEZ

E-mail: alfonso.calles-sanchez @ec.europa.eu

European Commission B-1049 Brussels

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DATA CONCERNING THE ACCURACY OF REPRESENTATIVE SURVEYS

### INSTITUT FÜR DEMOSKOPIE ALLENSBACH

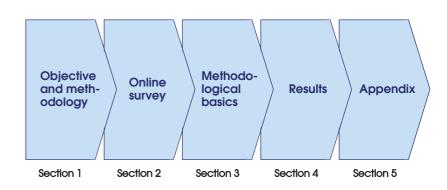
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## Contents

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## Objective and methodology

Objective In 2017, an evaluation of the overall state of the system of Supplementary Protection Certificates is being completed jointly by the EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES, Brussels (BE)<sup>1</sup> and the MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION, Munich (DE).

> One of the core elements of the evaluation is a survey among the stakeholders in the SPC system, i.e. persons who deal with Supplementary Protection Certificates (SPCs) in all EU Member States, including -

#### Target public

- Companies active in the pharmaceutical sector,
- Industrial associations in the pharmaceutical sector or professional associations,
- > Law firms or patent law firms,
- Universities and research institutions.

The survey focused on their experiences with the SPC system, their assessments of its current state and their recommendations for its future development.

The following report presents the findings of the survey, which was conducted by the INSTITUT FÜR DEMOSKOPIE ALLENSBACH, Allensbach (DE) in collaboration with the INSTITUT FÜR ANGEWANDTE DATENANALYSE (IFAD), Hamburg (DE).

<sup>&</sup>lt;sup>1</sup> Tender No. 55 /IMA/15/15153

#### Fieldwork

The survey was conducted as an online survey (CAWI),<sup>2</sup> with data being collected from May 22 to June 23, 2017. The deadline for responding was extended once for an additional 14 days.

#### Sample

The survey was a complete survey of an address file of preselected potential respondents provided by the MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION (pre-contacted contact persons, email addresses).

The sampling unit was the individual (company or office), not SPC applications. The final dataset comprises 203 completed questionnaires.

#### Responsibilities

The MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION provided the address data file but was—in accordance with the data protection laws and binding rules of professional conduct in Germany—not informed about which persons/firms/entities included on the original list ultimately took part in the survey and which did not. In documenting the respondents' verbatims in the pertinent section of this report, IFD ALLENSBACH made sure that neither the individuals nor the firms/other entities the respondents work with are recognizable from their answers.

IFD ALLENSBACH assumes the overall responsibility for the concept of the survey itself, that is, its methodology, and was also responsible for translating the research questions into test questions, supervising the fieldwork, ensuring the quality of the work completed by the fieldwork agency (IFAD) and reporting the findings. IFAD was commissioned to program the survey interface, conduct the fieldwork and deliver the data set.

<sup>&</sup>lt;sup>2</sup> Computer Assisted Web Interviewing

#### Data collection

Prospective respondents were sent an invitation by email containing a link to the online survey along with a personal codeword.

Respondents were free to call up and complete the online survey at a time of their own choosing. Respondents received up to two reminders.

The online interviews were conducted using an online questionnaire that automatically proceeded from one question to the next.

After receiving numerous requests, all respondents were sent the full written questionnaire as a PDF file on June 9, 2017.

The invitation, reminders and questionnaire were written in English. The questionnaire comprised 63 questions that were posed to the representatives of companies and 53 questions that were directed at the representatives of law firms, while the representatives of universities and research institutions were asked to answer a total of 46 questions, and the representatives of associations a total of 44 questions (excluding statistical questions).

Questionnaire The question wording was developed in close collaboration with the MAX PLANCK INSTITUTE. The topics of interest, along with the various aspects that were to be investigated more closely, were provided by the MAX PLANCK INSTITUTE in the form of a detailed list of so-called "research questions." The methodological transformation of these research questions into the actual test questions was completed by the Allensbach Institute's experienced and specialized team of questionnaire developers.

> In constructing the questionnaire, various question models and response formats were employed, namely, both so-called "open-ended" questions, for which no pre-formulated response alternatives are

provided and which thus require respondents to freely formulate their replies themselves, and "closed" questions, for which a selection of response alternatives is provided, including statements, lists of various items, different types of scales, etc.

Since the questionnaire was aimed at different groups of stakeholders, so-called "filters" were incorporated so as to ensure that the various groups were only asked to reply to those questions that were answerable and relevant given their specific area of knowledge and professional expertise.

A number of closed questions, especially those pertaining to potentially controversial issues, were accompanied by a comment box, thus enabling respondents to enter additional comments on a particular question. At the end of the questionnaire, respondents were also provided with space to enter any additional comments they might still have (Final question 77).

Since the information obtained via some questions determined the further course of the interview, these questions were mandatory, that is, respondents had to enter a response. All other questions could be left unanswered if the respondent preferred to do so.

#### Survey documentation

The following report presents selected main findings (highlights) in graphic form plus the complete results in tabular form. Details on the number of respondents, the statistical composition of the sample and the methodological approach employed to complete the study are provided in the appendix, which also includes a complete printout of the online questionnaire employed.

## Online survey

The online survey technique is a particularly appropriate and useful method for data collection when surveying smaller, specialised professional circles listed in a reliable database.

Quality requirements An important requirement to ensure the quality of the survey is that the members of the professional group to be surveyed must be reachable by email and accustomed to dealing with the Internet in a professional context. This requirement is fulfilled in the present investigation, since the vast majority of potential respondents do in fact use the Internet intensively in the course of their day-to-day work.

> To adequately assess the quality of the findings ascertained by the present online survey, the following aspects should be considered:

#### Response rate

Survey quality is often evaluated in view of the so-called "response rate" (completed interviews as a percentage of the net sample). Online surveys typically obtain much lower response rates than traditional survey methods, such as face-to-face or telephone interviewing, but this is not necessarily indicative of lower quality. The response rate calculated for the present online survey is 66 percent, a very satisfying result (details on how the response rate was calculated are provided in the appendix).

Response rates obtained for online interviews can only be compared to a limited extent with those obtained for face-to-face or telephone interviews. The way in which response rates are calculated is stricter when applied to online interviews, since the reasons for nonresponses can hardly be divided with complete certainty into quality-neutral and non-neutral categories, as can be done with other types of interviews. In the case of online research, all nonresponses with no feedback have to be classified as "non-neutral" in terms of quality. Even if substantialalbeit non-quantifiable—shares of such nonresponses are actually "quality-neutral" (for example, incorrect email addresses), they have to be deducted from the response rate.

In online survey samples, active respondents with above-average interest in and more distinct views on the topic being investigated tend to be overrepresented. Conversely, users with below-average interest in the topic and less distinct attitudes tend to be underrepresented. However, in online surveys conducted among professional groups, as is the case here, this effect tends to be less pronounced compared with online surveys aimed at the general public. Furthermore, the present survey aims to gather assessments, opinions and proposals rather than measuring the absolute magnitude of any assessment in percentages. In any case, the results do not underestimate any distinct opinions—and this applies to both positive and negative views.

## Methodological basics

### tables

Notes on how to read the The following notes explain some of the terms used in the computer tables in Section 4.2.

> As a rule, the findings in the tables refer to all respondents. If a question was only posed to a subgroup of respondents, or if a table only includes the findings calculated for a certain subgroup, this subgroup is indicated right below the question wording at the top of the table.

> The compilation may include some tables in which the sum of percentages is more than 100.0. In such cases, this means that respondents were able to give more than one response to a particular question. In a few instances, the sum of the findings is slightly less or more than 100.0 percent, a difference caused by rounding the findings up or down, which can lead to slight discrepencies that are not adjusted by the computer program when calculating the total result.

> The symbol "-" in the tables indicates that the corresponding response was not given by any respondents.

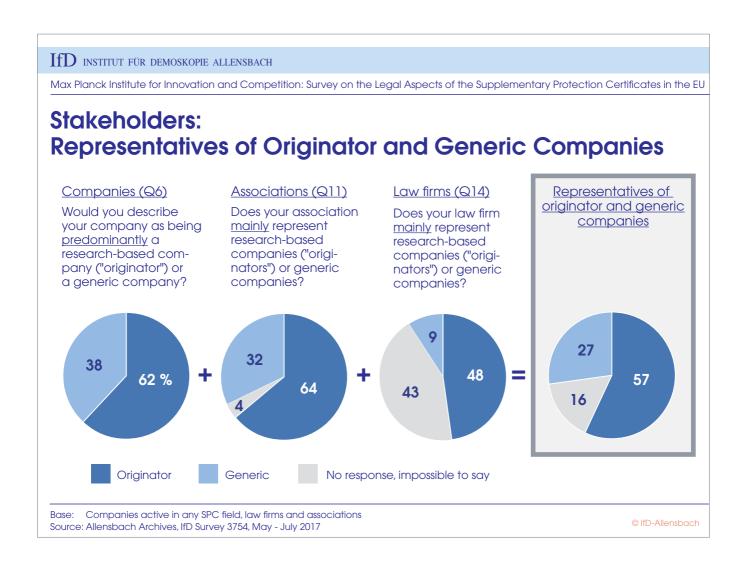
## Respondents' verbatims and comments

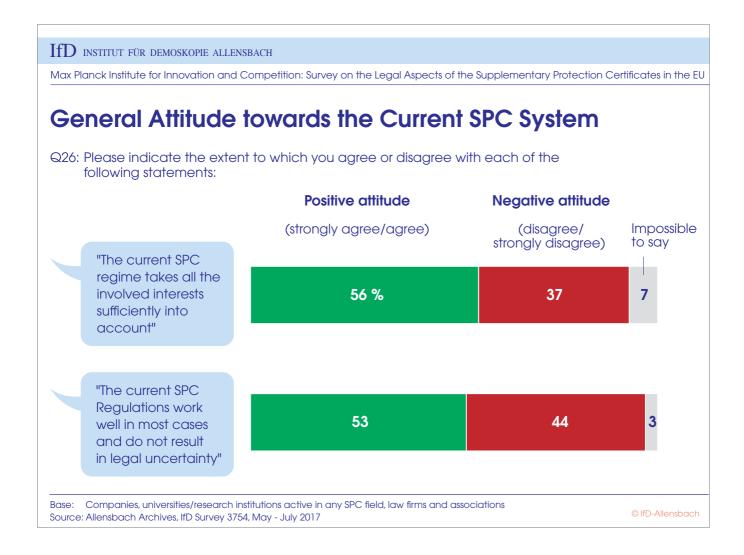
A substantial number of questions in the present survey were so called "open-ended" questions. Such questions provide no pre-formulated response alternatives, but instead collect respondents' verbatim replies. Furthermore, a substantial number of the closed questions with response alternatives were accompanied by a comment box where respondents could enter additional comments.

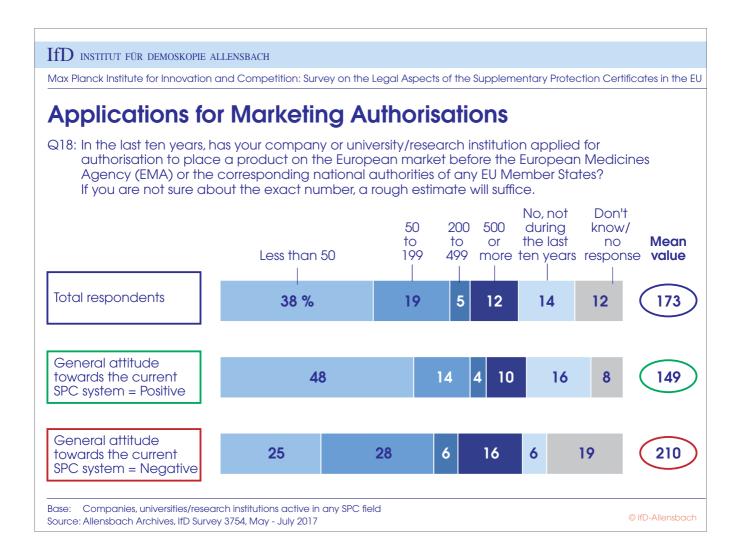
The remarks printed in the section 4.3 are quotations of the answers and comments: that is, they are cited exactly as entered by respondents so as not to alter the intended meaning and style in any way.

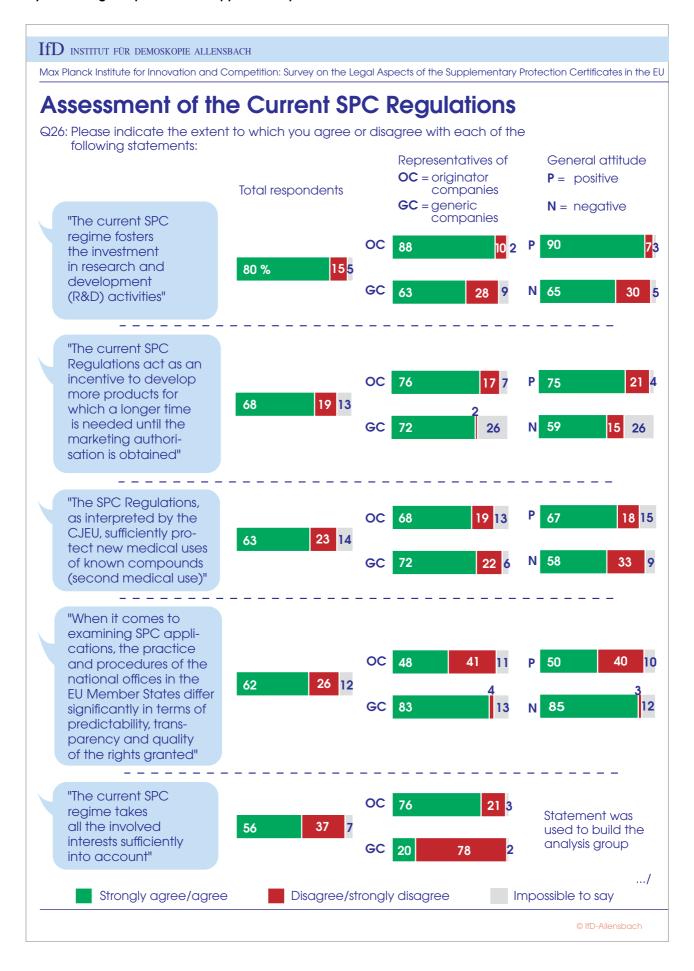
## 4 Results

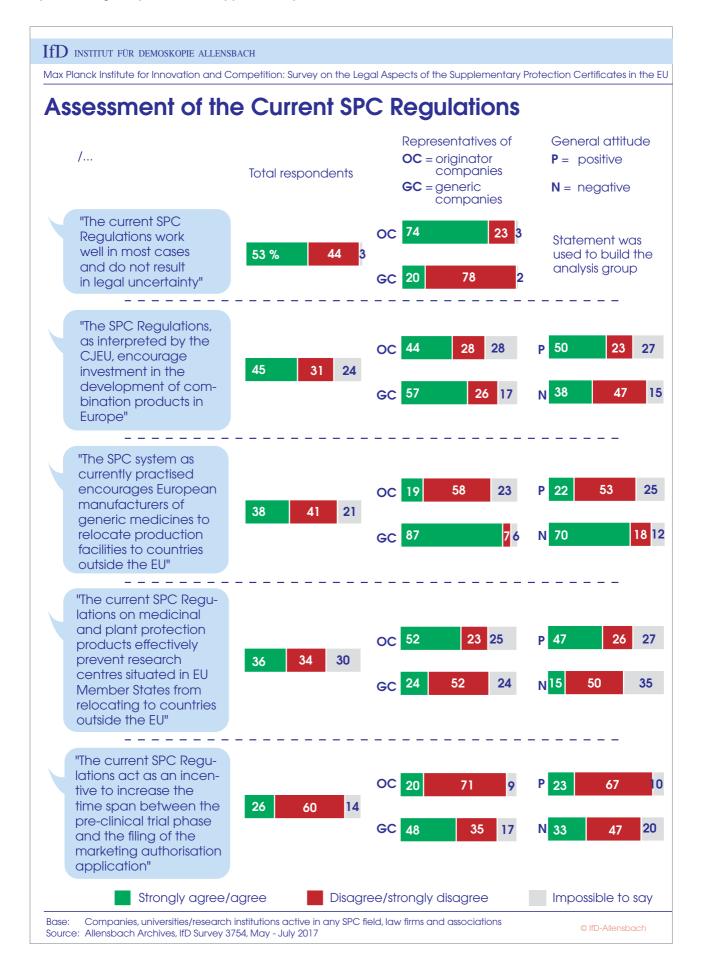
## 4.1 Highlights from the results in graphic form

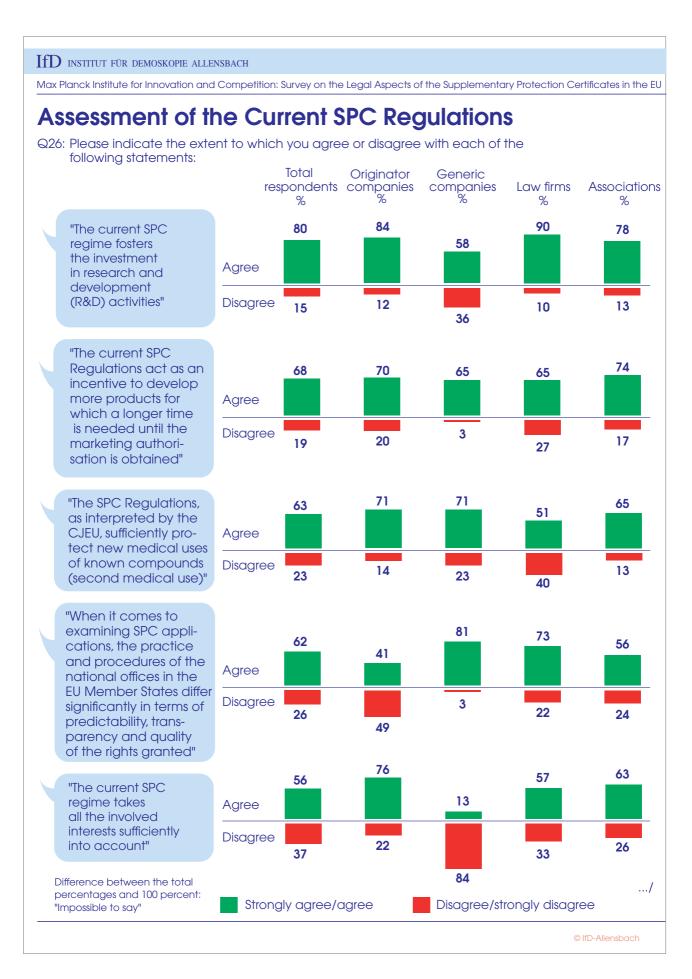


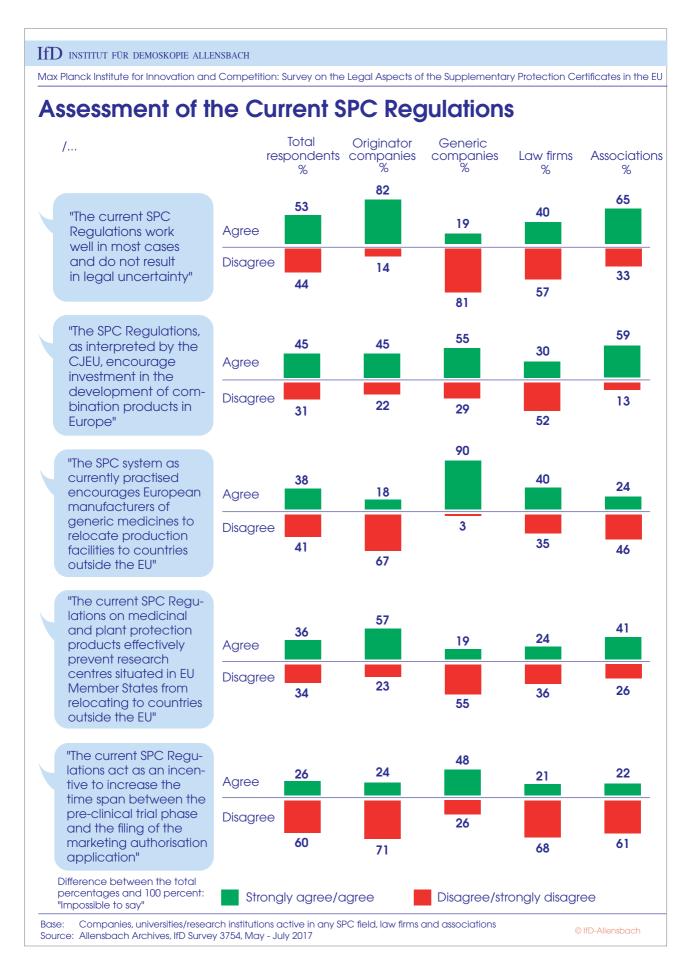


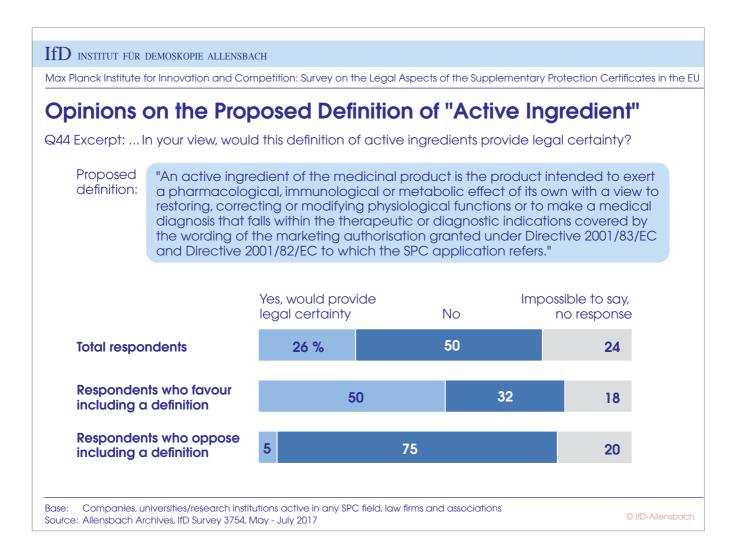


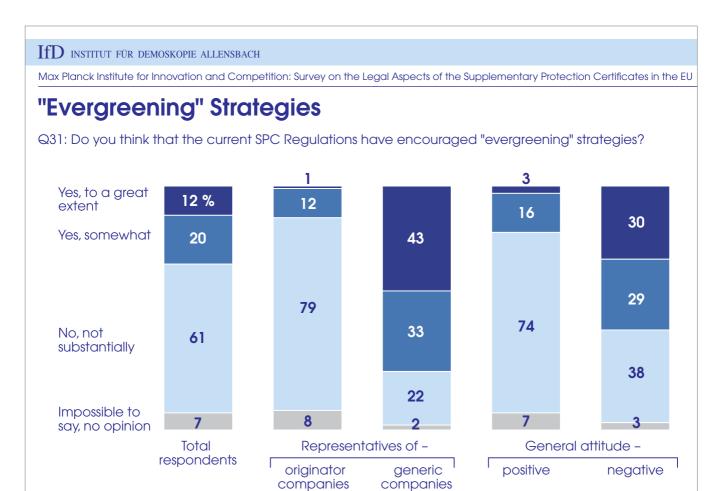












Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

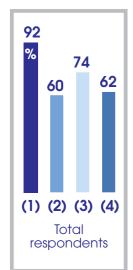
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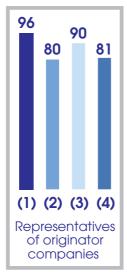
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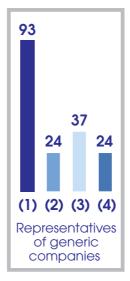
### **Development Activities**

Q33: In your opinion, which of the following development activities should be covered by SPCs?

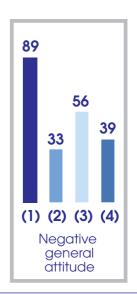
- (1) The development of <u>new active ingredients</u>
- (2) The development of <u>new formulations</u> of existing active ingredients
- (3) The development of <u>new indications</u> for existing active ingredients
- (4) The development of <u>new derivatives</u> of existing active ingredients



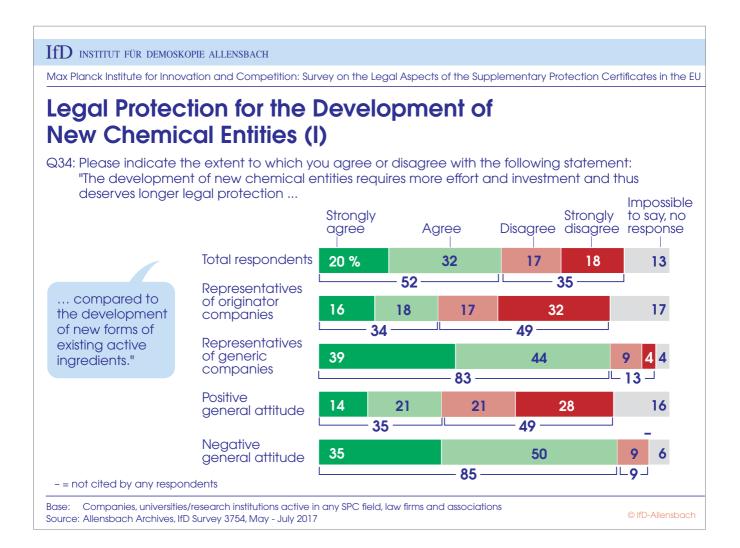


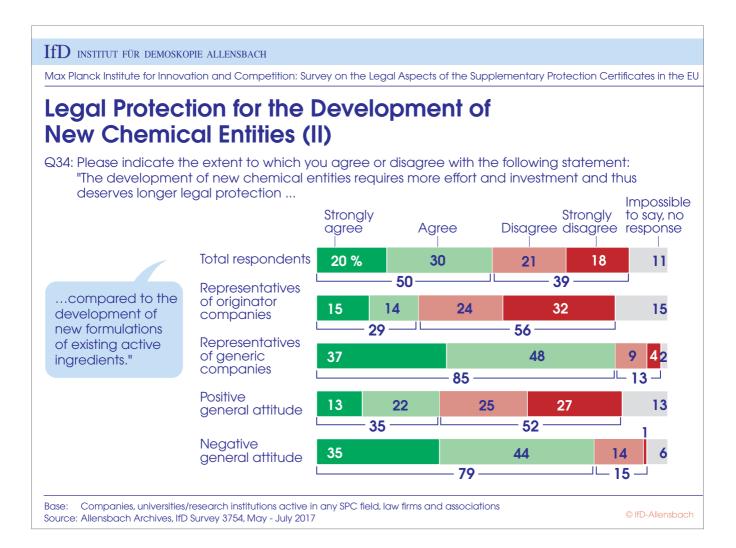


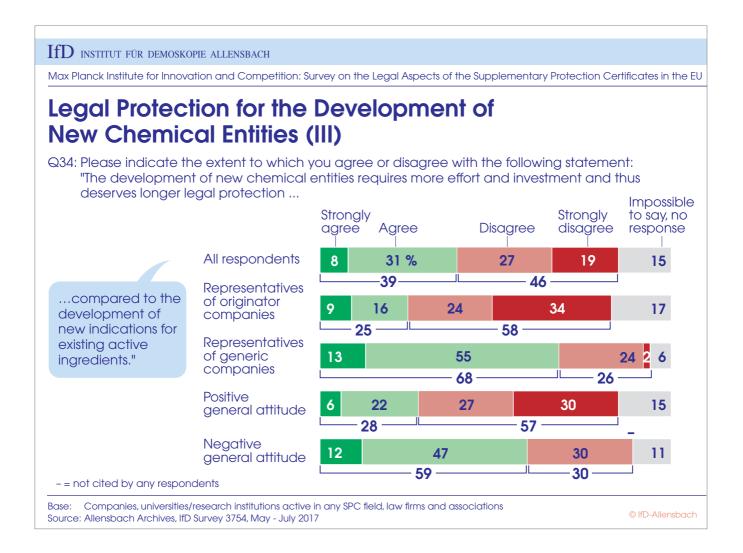




Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017





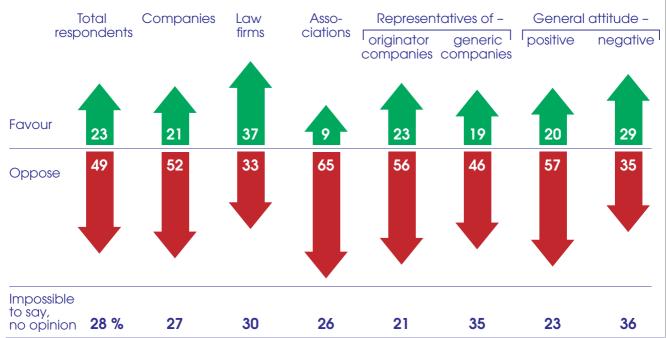


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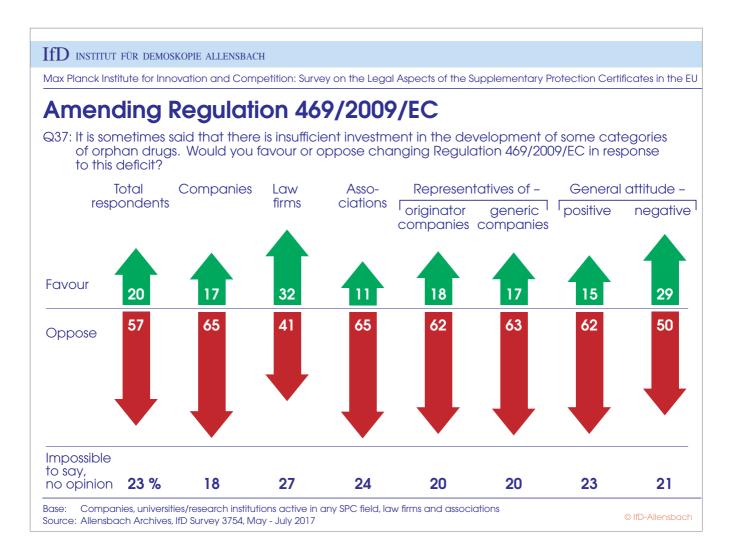
### **Amending Regulation 469/2009/EC**

Q35: It is sometimes said that there is insufficient investment in the development of new antibiotics. Would you favour or oppose changing Regulation 469/2009/EC in response to this assumed deficit?



Base: Companies, universities/research institutions active in any SPC field, law firms and associations

Source: Allensbach Archives, IfD Survey 3754, May - July 2017



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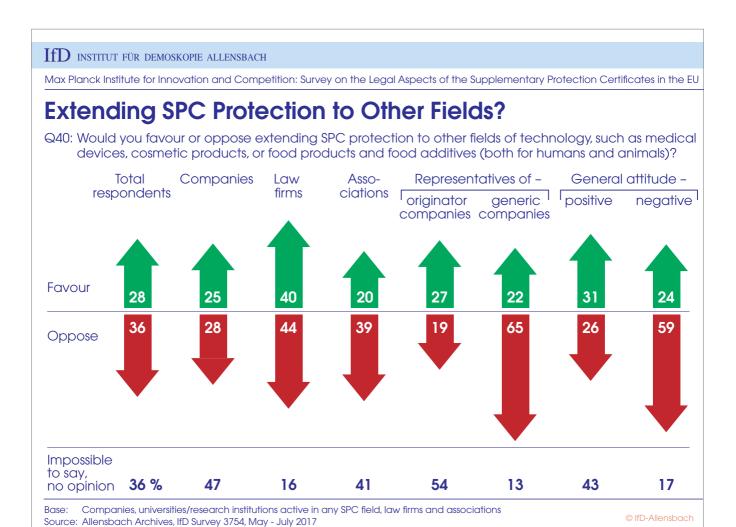
### **Amending Regulation 469/2009/EC**

Q39: Regulation 469/2009/EC was conceived in view of new molecules, new applications and new manufacturing methods. The pharmaceutical industry is now increasingly investing in new formulations of existing drugs, new delivery systems and combination products. Taking this into account, would you favour or oppose amending the Regulation in this regard?



Base: Companies, universities/research institutions active in any SPC field, law firms and associations

Source: Allensbach Archives, IfD Survey 3754, May - July 2017



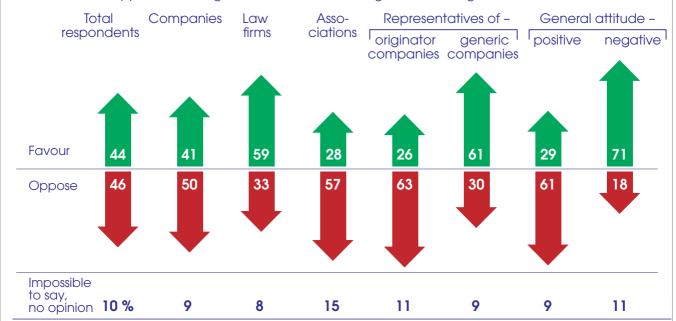
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Max Planck Institute for Innovation and Competition: Survey on the Legal Aspects of the Supplementary Protection Cer							
Products That Should	Receive SPC Protection						
Q41: To which types of products would you favour extending the current SPC protection?							
Medical devices	91 %						
Cosmetic products	43						
·							
Food additives	38						
Food products	34						
·							
Other	16						
Base: Respondents who favour extending the cur	rent SPC protection	_					
Source: Allenshach Archives IfD Survey 3754 May	□ IrD-Allensba	ch					

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# Should a Definition of "Active Ingredient" Be Included in Regulation 469/2009/EC?

Q43: Regulation 469/2009/EC does not define the concept of "active ingredient". All in all, would you favour or oppose including a definition of "active ingredient" in Regulation 469/2009/EC?



Base: Companies, universities/research institutions active in any SPC field, law firms and associations

Source: Allensbach Archives, IfD Survey 3754, May - July 2017

#### IfD institut für demoskopie allensbach Max Planck Institute for Innovation and Competition: Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU **Opinions on the Proposed Definition of "Active Ingredient"** Q44 Excerpt: ... In your view, would this definition of active ingredients provide legal certainty? Proposed "An active ingredient of the medicinal product is the product intended to exert definition: a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/83/EC and Directive 2001/82/EC to which the SPC application refers." Yes, would provide Impossible to say, legal certainty No no response 50 **Total respondents** 26 % 24

50

75

32

Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

Respondents who favour

Respondents who oppose

including a definition

including a definition

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18

20

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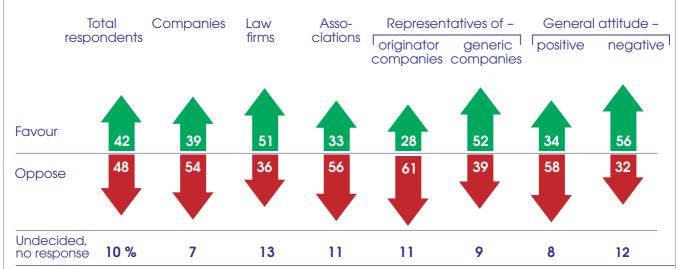
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## **Opinions on the Proposed Clarification Concerning Derivatives**

Q45 Excerpt: ... All in all, would you favour or oppose this clarification?

Proposed clarification:

"The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless they differ significantly in properties with regard to safety and/or efficacy", see Art. 10(2)(b) Directive 2001/83/EC



Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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## Attitudes towards the CJEU Case Law on Art. 3(a) and (b) of Regulation 469/2009/EC and Regulation 1610/96/EC

Q46: Our next question pertains to the CJEU case law on Art. 3(a) and (b) of Regulation 469/2009/EC and 1610/96/EC: According to the CJEU, a product is protected by the basic patent within the meaning of Art. 3(a) SPC Regulations when it is specified in the wording of the claims of the basic patent (see, for instance, decision C-322/10 – Medeva)

In your opinion, to what extent does this case law provide a clear criterion for deciding on SPC applications and/or resolving legal disputes?

			<b>Unclear criterion</b>		Clear criterion	
	Mean value	2	<u>-1</u> )	<b>10</b>	1	2
Total respondents	-0.15					
Companies	0.43					
Law firms	-1.03					
Associations	0.00					
Representatives of – originator companies	0.34					
generic companies	-0.30					
General attitude - positive negative	0.23 -0.82					

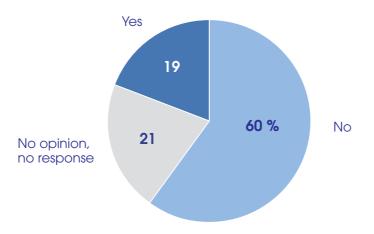
Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

#### IfD INSTITUT FÜR DEMOSKOPIE ALLENSBACH Max Planck Institute for Innovation and Competition: Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Amending the Regulation in Order to Ensure Greater **Legal Certainty** Q48: When it comes to Art. 3 (a) of Regulation 469/2009/EC and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty? A new paragraph in the Regulations with the following wording: "The product is protected by a basic patent in force when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC and corresponding national provisions and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed." According to this, the SPC may only be granted for subject matter to which the basic patent may be limited without violating Art. 123(2) EPC(1) or the corresponding national provisions 12 % 13 17 10 16 A new paragraph with the following wording: "The product is protected when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC or the corresponding national provisions." This would be an infringement test. 21 13 39 20 18 26 A new paragraph providing a "core inventive advance test" (as in UK case law) whereby the subject matter of the SPC is protected by the basic patent when two requirements are cumulatively met: it falls under the scope of protection of the patent AND it represents the core inventive advance of the invention 19 15 43 10 33 No amendment of Art. 3 (a) SPC Regulation is needed 44 38 58 56 20 55 16 No opinion, impossible to say, no response 11 13 10 10 15 17 General attitude -Total Representatives of -Comlaw Assorespondents panies firms ciations originator positive generic negative | companies companies Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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## Should Changes That Require an Extension of the Marketing Authorisation Be Considered to Be a New **Marketing Authorisation?**

Q50: In your opinion, should changes that require an extension of the marketing authorisation be considered to be a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?



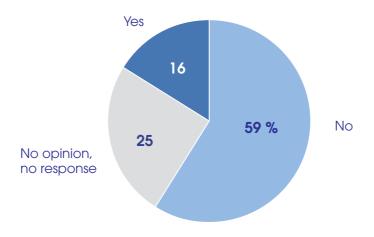
Base: Companies active in any SPC field and law firms Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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## Should Any "Type II Variation" Constitute a New Marketing **Authorisation?**

Q51: Regulation 1234/2008/EC refers to three types of variations which have different implications depending on the likely impact of the change on the quality, safety or efficacy of the medicinal product. This includes "type II variations", that is, major variations that do not constitute an extension and which may have a significant impact "on the quality, safety or efficacy" of the medicinal product concerned. In your view, should any "type II variation" constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?



Base: Companies active in any SPC field and law firms Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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### **Patent Extensions**

Q56: In Europe it is not possible to obtain an SPC if the patent expires before the marketing authorisation has been granted. By contrast, in the United States it is possible to obtain a patent extension even if the patent expires before the marketing authorisation has been granted. The patent holder can in fact file an application for an interim extension before the expiration date of the patent. In practice, do you favour amending the EU Regulations in this regard?

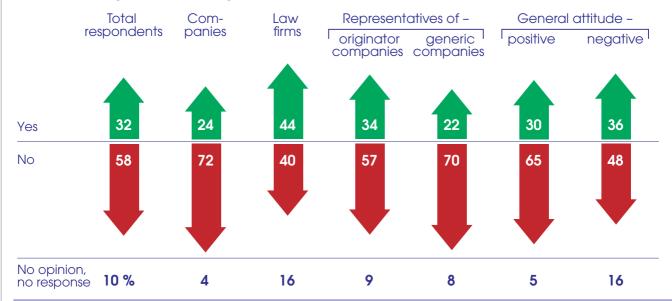


Base: Companies active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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## Should It Be Possible to Obtain an SPC if the Patent Was Granted after the Expiration Date of the Patent Itself?

Q57: In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself. In practice, do you favour amending the EU Regulations in this regard?

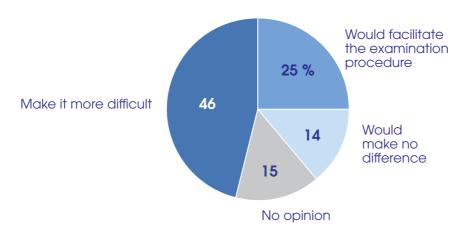


Base: Companies active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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## Should the Subject Matter for Which Protection Is Sought Already Be Specified in the SPC Application?

Q58: Patent claims are statements that define the matter for which protection is sought in terms of the technical features of the invention. So far, Regulation 469/2009/EC does not seem to provide that such statements should be included in the SPC application. If the subject matter for which protection is sought had to be specified already in the SPC application in a form similar to patent claims: Do you think that this would facilitate the examination procedure or, on the contrary, make it more difficult, or do you think it would make no difference?



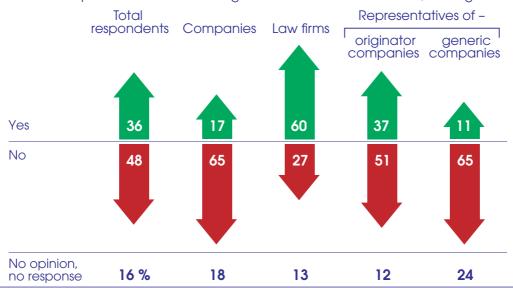
Base: Companies active in any SPC field and law firms Source: Allensbach Archives, IfD Survey 3754, May - July 2017

#### IfD institut für demoskopie allensbach Max Planck Institute for Innovation and Competition: Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Measures Expected to Have a Positive Impact Q59: Which of the following measures would you expect to have a positive impact? Please mark all applicable measures. Total Representatives of -General attitude respondents originator generic positive negative I companies companies If the procedures for granting SPCs were harmonised within the EU 88 % 88 89 87 89 If third parties had the right to file observations like in proceedings before the EPO under Art. 115 EPC 41 76 66 27 If the examination of all requirements provided under Art. 3 of the SPC 41 Regulations was made mandatory 57 30 62 26 If oppositions against SPCs were made possible in cases where the right was granted in violation of Art. 3 of the Regulations 41 68 60 27 30 I do not expect any of the above 4 6 3 4 4 to have a positive impact Base: Companies active in any SPC field and law firms Source: Allensbach Archives, IfD Survey 3754, May - July 2017

Max Planck Institute for Innovation and Competition: Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

## Suggestions for New Rules in Both SPC Regulations Analogous to Some EPC Rules

Q60: There are suggestions for new rules in both SPC Regulations (Regulation 469/2009/EC and Regulation 1610/96/EC) analogous to some EPC rules. Which of the following rules would you welcome under SPC Regulations? First, would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC?

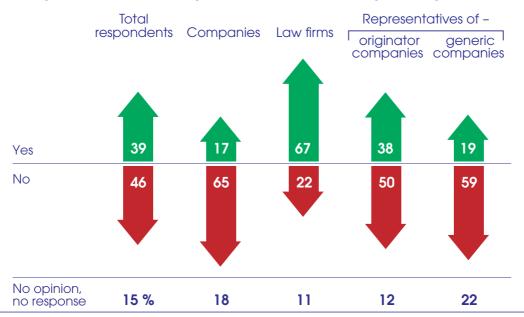


Base: Companies active in any SPC field and law firms Source: Allensbach Archives, IfD Survey 3754, May - July 2017

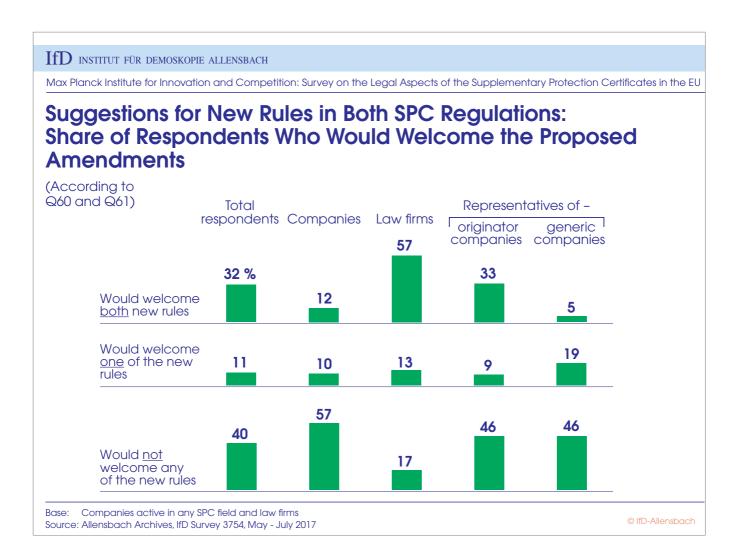
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## Suggestions for New Rules in Both SPC Regulations Analogous to Some EPC Rules

Q61: Secondly, would you welcome a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138 (3) EPC?



Base: Companies active in any SPC field and law firms Source: Allensbach Archives, IfD Survey 3754, May - July 2017



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# Does the Availability of SPC Protection Affect Companies' Decisions About Where to Produce Active Ingredients?

Q63: Does the availability of SPC protection affect your company's decisions about where, in which country, to produce active ingredients?

	Total respondents	Originator ompanies	Generic ompanies
Yes	25	6	55
No	18	29	-
Varies from case to case	e <b>50</b>	59	35
No opinion	7 %	6	10

- = not cited by any respondents

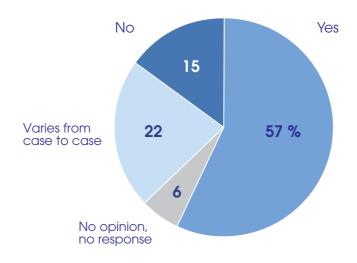
Base: Companies active in any SPC field

Source: Allensbach Archives, IfD Survey 3754, May - July 2017

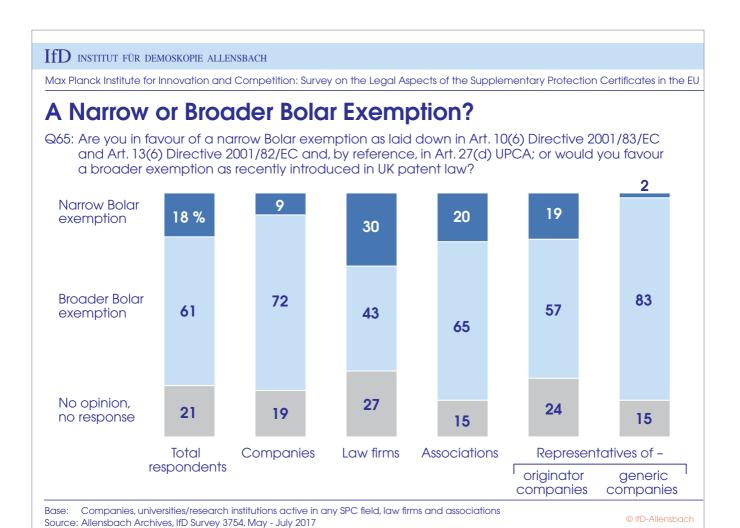
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## Does the Scope of the Bolar Exemption Influence Decisions on Where to Conduct Pre-Clinical and Clinical Trials?

Q64: Is the scope of the Bolar exemption in the case law of a given country a relevant factor for you when deciding where to conduct pre-clinical and clinical trials?



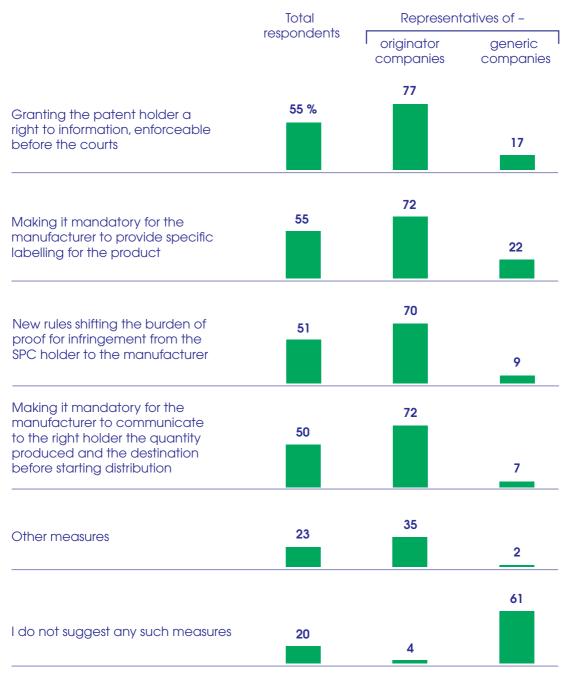
Base: Companies active in any SPC field Source: Allensbach Archives, IfD Survey 3754, May - July 2017



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# Measures to Prevent Stockpiling or Exportation If a Manufacturing Waiver Were to Be Introduced

Q68: Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force?



Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

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## Is There a Need for a "Unitary SPC"?

Q69: The creation of a "unitary SPC" which can be obtained with a single granting procedure is currently under consideration. In your opinion, is there actually a need for creating a "unitary SPC" or is there no actual need?



Base: Companies, universities/research institutions active in any SPC field, law firms and associations Source: Allensbach Archives, IfD Survey 3754, May - July 2017

#### IfD INSTITUT FÜR DEMOSKOPIE ALLENSBACH Max Planck Institute for Innovation and Competition: Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU **Authority That Should Grant a "Unitary SPC"** Q70: In your opinion, which authority shown on this list should grant a "unitary SPC"? Total Representatives of respondents originator generic companies companies 71 54 % A virtual patent office created based 23 on new EU rules and composed of examiners from national patent offices 25 25 21 The EPO 13 An EU authority such as the EU 8 4 Intellectual Property Office (EUIPO) 23 An EU authority such as the 7 1 European Medicines Agency (EMA)

6

3

Base: All respondents who, in response to Q69, replied that "Yes, there is actually a need" for creating a "unitary SPC" Source: Allensbach Archives, IfD Survey 3754, May - July 2017

National patent offices based

on a mutual recognition system

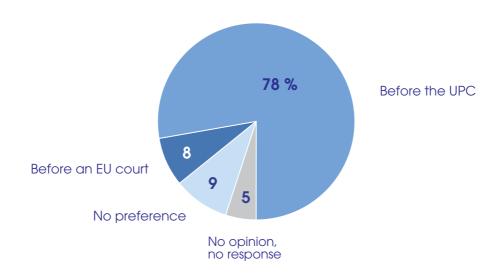
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## Where Should the Decisions of the Body That Grants a "Unitary SPC" Be Subject to Appeal?

Q74: In your view, should the decisions of the body that grants a "unitary SPC" be subject to appeal before the Unified Patent Court (UPC) or before an EU court, such as the Court of First Instance, as in the case with EU trade marks or designs?



Base: All respondents who, in response to Q69, replied that "Yes, there is actually a need" for creating a "unitary SPC" Source: Allensbach Archives, IfD Survey 3754, May - July 2017



All respondents who, in response to Q69, replied that "Yes, there is actually a need" for creating a "unitary SPC"

Source: Allensbach Archives, IfD Survey 3754, May - July 2017

## 4.2 Complete results in tabular form

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		· ·	
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Ø06311011	37	l de la companya de	201
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······································		to Art. 138 (3) EPC?	
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			, >

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	3:	

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 1
Which of the following applies to you?
I represent a ...

Base = all respondents

		Total (without the				Representatives of				
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		ASSOCIATION	institution	companies	companies
Base	203	189	89	51	31	63	46	5	99	46
Company	43,84%	44,97%	100,00%	100,00%	100,00%	-	-	-	51,52%	67,39%
Association	22,66%	21,69%	-	-	-	-	100,00%	-	18,18%	19,57%
Law firm or patent law firm	31,03%	30,69%	-	-	-	100,00%	-	-	30,30%	13,04%
University or research institution	2,46%	2,65%	-	-	-	-	-	100,00%	-	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of	law firm	Con University/re	npany, Associat esearch institution	ion, on is located	C	ompanies by siz	ze	Position a	t company	Scope of activ	company ities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	203	21	41	64	48	6	14	20	53	19	53	70	15
Company	43,84%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Association	22,66%	-	-	-	-	-	-	-	-	-	-	-	-
Law firm or patent law firm	31,03%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-
University or research institution	2,46%	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Base: SPC Stakeholders

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 1
Which of the following applies to you?
I represent a ...

Base = all respondents

	Total	General attitude towards current SPC system			
		positiv	negativ		
Base	203	124	66		
Company	43,84%	40,32%	46,97%		
Association	22,66%	26,61%	18,18%		
Law firm or patent law firm	31,03%	33,06%	33,33%		
University or research institution	2,46%	-	1,52%		
No response	-	-	-		
Total	100,00%	100,00%	100,00%		

Base = all companies

		Total (without the				Representatives of				
	Total	later accepted partici-		Company			Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic	Law firm		institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
Austria Belgium Bulgaria Croatia	2,25% 3,37% - -	2,35% 3,53% - -	2,25% 3,37% - -	1,96% 1,96% - -	3,23% - - -	- - - -	- - - -	- - -	1,96% 1,96% - -	3,23% - - -
Cyprus Czech Republic Denmark Estonia Finland	1,12% 3,37% -	1,18% 3,53% -	1,12% 3,37%	5,88% - -	3,23% - -	- - - -	- - - -	-	5,88% -	3,23% - -
France Germany Greece Hungary	7,87% 16,85% 3,37% 2,25%	8,24% 16,47% 3,53% 2,35%	7,87% 16,85% 3,37% 2,25%	11,76% 17,65% - -	16,13% 9,68% 6,45%	- - - -	- - -	- - -	11,76% 17,65% - -	- 16,13% 9,68% 6,45%
Ireland Italy Latvia Lithuania	1,12% 5,62%	1,18% 5,88%	1,12% 5,62%	- 1,96% - -	3,23% 6,45%	- - -	- - -	- - -	1,96% -	3,23% 6,45% -
Luxembourg Malta The Netherlands		- - -	- - -	- - -	- - -	- - -	- - -	- - -	- - -	-
Poland Portugal Romania Slovakia	2,25% 1,12% - -	2,35% 1,18% - -	2,25% 1,12% - -	- - -	6,45% 3,23% - -	- - -	- - -	- - -	- - -	6,45% 3,23% - -
Slovenia Spain Sweden	1,12% 11,24%	1,18% 11,76% -	1,12% 11,24% -	5,88% -	3,23% 19,35% -	- - -	- - -	- - -	5,88% -	3,23% 19,35% -
United Kingdom Other country  No response	8,99% 28,09% -	9,41% 25,88%	8,99% 28,09% -	11,76% 41,18%	6,45% 12,90%	- - -	- -	- -	11,76% 41,18%	6,45% 12,90% -
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

Base = all companies

		Type of			npany, Associatesearch institution		С	ompanies by siz	ze	Position a	t company	Scope of activ	company rities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Austria	2,25%	-	-	3,13%	4,17%	-	-	10,00%	-	-	3,77%	2,86%	_
Belgium	3,37%	-	-	4.69%	6,25%	-	14,29%	-	1.89%	10,53%	1,89%	2.86%	6,67%
Bulgaria		-	-	-		-	-	-	-		-	-	-
Croatia	_	_	_	_	_	_	_	_	_	_	_	_	_
Cyprus	_	-	-	-	-	-	-	-	-	-	-	-	-
Czech Republic	1,12%	_	_ 1	1,56%	_	16,67%	_	_	1,89%	5,26%	-	1,43%	-
Denmark	3,37%	_	_ 1	4,69%	_		_	_	5,66%	- 5,2570	1,89%	4,29%	-
Estonia	3,3770	_	_	-,0070	_	_	_	_	3,0070	_	1,0370	-,2370	-
Finland	_	_	_	_	_	_	_	_	_	_	_	_	_
France	7,87%	_	_	10,94%	14,58%	_	14,29%	5,00%	7,55%	5,26%	11,32%	5,71%	13,33%
Germany	16,85%	_	_	23,44%	31,25%	_	21,43%	10,00%	18,87%	10,53%	18,87%	15,71%	20,00%
Greece	3,37%	_		4,69%	6,25%	_	7,14%	10,00%	10,0770	10,5570	5,66%	4,29%	20,0070
Hungary	2,25%	_	_	3,13%	0,2370	33,33%	7,1470	10,0070	3,77%	_	1,89%	1,43%	6,67%
Ireland	1,12%	-	_	1,56%	2,08%	33,3370	7,14%		3,1170	_	1,0970	1,43%	0,0770
Italy	5,62%	-	_	7,81%	10,42%	-	14,29%	15,00%	-	_	9,43%	1,43%	26,67%
Latvia	5,02%	-	_	7,0190	10,42%	-	14,29%	15,00%	-	_	9,43%	1,43%	20,0790
	-			-		-		-				-	-
Lithuania	-	-		-	-	-	-	-	-	-	-	-	-
Luxembourg	-	-	-	-	-	-	-	-	-	-	-	-	-
Malta	-	-	-	-	-	-	-	-	-	-	-	-	-
The Netherlands		-	-	-	-	-	-	-	-		-	-	-
Poland	2,25%	-	-	3,13%	-	33,33%	-	-	3,77%	5,26%	1,89%	1,43%	6,67%
Portugal	1,12%	-	-	1,56%	2,08%	-	-	5,00%	-	5,26%	-	1,43%	-
Romania	-	-	-	-	-	-	-	-	-	-	-	-	-
Slovakia		-	-	-	-	-	-	-	-	-	-	-	-
Slovenia	1,12%	-	-	1,56%	2,08%	16,67%			1,89%		-	1,43%	-
Spain	11,24%	-	-	15,63%	20,83%	-	7,14%	30,00%	5,66%	10,53%	11,32%	12,86%	6,67%
Sweden	-	-	-	-	-	-	-	-	-	-	-	-	-
United Kingdom	8,99%	-	-	12,50%	-	-	14,29%	10,00%	7,55%	10,53%	7,55%	8,57%	13,33%
Other country	28,09%	-	-	-	-	-	-	5,00%	41,51%	36,84%	24,53%	32,86%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Base = all companies

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	89	50	31			
Austria	2,25%	2,00%	3,23%			
Belgium	3,37%	2,00%	-			
Bulgaria	-	-	-			
Croatia	-	-	-			
Cyprus	-	-	-			
Czech Republic	1,12%	-	3,23%			
Denmark	3,37%	6,00%	-			
Estonia	-	-	-			
Finland		40.000/	-			
France	7,87%	10,00%	-			
Germany	16,85%	18,00%	16,13%			
Greece	3,37%	-	9,68%			
Hungary	2,25%	2.000/	6,45%			
Ireland	1,12%	2,00%	- 0.450/			
Italy   Latvia	5,62%	2,00%	6,45%			
Lithuania	-	-	-			
	-	-	-			
Luxembourg Malta	-	-	-			
The Netherlands	-	-	-			
Poland	2,25%	-	6,45%			
Portugal	1,12%	_	3,23%			
Romania	1,1270	_	3,2370			
Slovakia	_	_	_			
Slovenia	1,12%	_	3,23%			
Spain	11,24%	10,00%	12,90%			
Sweden	,- : 70	,	,			
United Kingdom	8,99%	10,00%	9,68%			
Other country	28,09%	38,00%	19,35%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

#### Base = all companies

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-	Company		Law firm			Originator	Generic		
		pants)	Total	Originator	Generic			Research institution	companies	companies	
Base	89	85	89	51	31	-	-	-	51	31	
Total EU 28	71,91%	74,12%	71,91%	58,82%	87,10%	-	-	-	58,82%	87,10%	
EZ 19	53,93%	55,29%	53,93%	41,18%	64,52%	-	-	-	41,18%	64,52%	
New Member States since 2004	6,74%	7,06%	6,74%	-	19,35%	-	-	-	-	19,35%	
Outside of the EU	28,09%	25,88%	28,09%	41,18%	12,90%	-	-	-	41,18%	12,90%	
No response	-	-	-	-	-	-	-	-	-	-	

	Type of law firm		law firm	Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Total EU 28	71,91%	-	-	100,00%	100,00%	100,00%	100,00%	95,00%	58,49%	63,16%	75,47%	67,14%	100,00%
EZ 19	53,93%	-	-	75,00%	100,00%	16,67%	85,71%	85,00%	35,85%	42,11%	62,26%	50,00%	73,33%
New Member States since 2004	6,74%	-	-	9,38%	2,08%	100,00%	-	-	11,32%	10,53%	3,77%	5,71%	13,33%
Outside of the EU	28,09%	-	-	-	-	-	-	5,00%	41,51%	36,84%	24,53%	32,86%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-

Base = all companies

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	89	50	31			
Total EU 28	71,91%	62,00%	80,65%			
EZ 19	53,93%	46,00%	54,84%			
New Member States since 2004	6,74%	-	19,35%			
Outside of the EU	28,09%	38,00%	19,35%			
No response	-	-	-			

#### Ouestion 3

Is the company entity you represent active in a field for which SPC (Supplementary Protection Certificate) protection is available?

#### Base = all companies

		Total (without the				Representatives of					
	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	89	85	89	51	31	-	-	-	51	31	
Yes	92,13%	91,76%	92,13%	100,00%	100,00%	-	-	-	100,00%	100,00%	
No	7,87%	8,24%	7,87%	-	-	-	-	-	-	=	
No response	-	-	-	<del>-</del>	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%	

	Type of law firm		law firm	Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Yes	92,13%	-	-	89,06%	85,42%	100,00%	64,29%	95,00%	98,11%	89,47%	92,45%	95,71%	73,33%
No	7,87%	-	-	10,94%	14,58%	-	35,71%	5,00%	1,89%	10,53%	7,55%	4,29%	26,67%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

#### Ouestion 3

Is the company entity you represent active in a field for which SPC (Supplementary Protection Certificate) protection is available?

Base = all companies

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	89	50	31			
Yes	92,13%	100,00%	100,00%			
No	7,87%	-	-			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 4 What is your company's sector of activity? (Multiple responses possible)

Base = all companies active in any SPC field (according to Q3)

		Total							Representatives of		
	Total	(without the later accepted		Company			Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic	Law firm		institution	companies	companies	
Base	82	78	82	51	31	-	-	-	51	31	
Pharmaceuticals (humans)	91,46%	91,03%	91,46%	92,16%	90,32%	-	-	-	92,16%	90,32%	
Pharmaceuticals (animals)	15,85%	15,38%	15,85%	19,61%	9,68%	-	-	-	19,61%	9,68%	
Plant protection	8,54%	8,97%	8,54%	7,84%	9,68%	-	-	-	7,84%	9,68%	
Sum of answers	115,85%	115,38%	115,85%	119,61%	109,68%	-	-	-	119,61%	109,68%	
No response	-	-	-	-	-	-	-	-	-	-	

		Type of law firm		Company, Association, University/research institution is located			C	ompanies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	82	-	-	57	41	6	9	19	52	17	49	67	11
Pharmaceuticals (humans)	91,46%	-	-	91,23%	87,80%	100,00%	100,00%	84,21%	92,31%	94,12%	87,76%	91,04%	90,91%
Pharmaceuticals (animals)	15,85%	-	-	19,30%	21,95%	16,67%	55,56%	10,53%	11,54%	17,65%	10,20%	14,93%	18,18%
Plant protection	8,54%	-	-	8,77%	12,20%	-	-	10,53%	9,62%	-	12,24%	8,96%	9,09%
Sum of answers	115,85%	-	-	119,30%	121,95%	116,67%	155,56%	105,26%	113,46%	111,76%	110,20%	114,93%	118,18%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 4 What is your company's sector of activity? (Multiple responses possible)

Base = all companies active in any SPC field (according to Q3)

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	82	50	31
Pharmaceuticals (humans)	91,46%	90,00%	93,55%
Pharmaceuticals (animals)	15,85%	24,00%	3,23%
Plant protection	8,54%	8,00%	9,68%
Sum of answers	115,85%	122,00%	106,45%
No response	-	-	-

Base = all companies active in any SPC field (according to Q3) and more than one answer in Q4

		Total				Representatives of				
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	12	11	12	9	3	-	-	-	9	3
Pharmaceuticals (humans)	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Pharmaceuticals (animals)	-	-	-	-	-	-	-	-	-	-
Plant protection	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

	Type of law firm			Con University/re	npany, Associat search institutio	ion, on is located	C	ompanies by siz	re	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	12	-	-	10	8	1	5	1	6	2	5	9	2
Pharmaceuticals (humans)	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Pharmaceuticals (animals)	-	-	-	-	-	-	-	-	-	-	-	-	-
Plant protection	-	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 5 What is your company's main sector of activity?

Base = all companies active in any SPC field (according to Q3) and more than one answer in Q4

	Total	General attit current SF	
		positiv	negativ
Base	12	10	2
Pharmaceuticals (humans) Pharmaceuticals (animals) Plant protection	100,00%	100,00% - -	100,00% - -
No response	-	-	-
Total	100,00%	100,00%	100,00%

Question 6
Would you describe your company as being predominantly a research-based company ("originator") or a generic company?

Base = all companies active in any SPC field (according to Q3)

		Total (without the				Representatives of				
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.00.00	institution	companies	companies
Base	82	78	82	51	31	-	-	-	51	31
Originator	62,20%	61,54%	62,20%	100,00%	-	-	-	-	100,00%	-
Generic	37,80%	38,46%	37,80%	-	100,00%	-	-	-	-	100,00%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	re	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	82	-	-	57	41	6	9	19	52	17	49	67	11
Originator	62,20%	-	-	52,63%	51,22%	-	66,67%	36,84%	71,15%	64,71%	59,18%	61,19%	63,64%
Generic	37,80%	-	-	47,37%	48,78%	100,00%	33,33%	63,16%	28,85%	35,29%	40,82%	38,81%	36,36%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 6
Would you describe your company as being predominantly a research-based company ("originator") or a generic company?

Base = all companies active in any SPC field (according to Q3)

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	82	50	31
Originator	62,20%	86,00%	22,58%
Generic	37,80%	14,00%	77,42%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 7 What type of association do you represent?

### Base = all associations

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-		Company	pany Law fi		Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	46	41	-	-	-	-	46	-	18	9	
Industry association	71,74%	73,17%	-	-	-	-	71,74%	-	100,00%	100,00%	
Professional association	19,57%	21,95%	-	-	-	-	19,57%	-	-	-	
Other association	8,70%	4,88%	-	-	-	-	8,70%	-	-	-	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	-	-	-	-	100,00%	-	100,00%	100,00%	

		Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	46	-	-	-	-	-	-	-	-	-	-	-	-
Industry association	71,74%	-	-	-	-	-	-	-	-	-	-	-	-
Professional association	19,57%	-	-	-	-	-	-	-	-	-	-	-	-
Other association	8,70%	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	-	1	-	-	-	-	-	-	-	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 7 What type of association do you represent?

Base = all associations

	Total	General attit current SF	ude towards PC system	
		positiv		
Base	46	33	12	
Industry association	71,74%	78,79%	58,33%	
Professional association	19,57%	15,15%	25,00%	
Other association	8,70%	6,06%	16,67%	
No response	-	-	-	
Total	100,00%	100,00%	100,00%	

Question 8
In which country is the association you represent located?

Base = all associations

		Total (without the			Type of st	akeholder			Representatives of	
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic	Law IIIII	7.00001411011	institution	companies	companies
Base	46	41	-	-	-	-	46	-	18	9
Austria	2,17%	2,44%	-	-	-	-	2,17%	-	_	11,11%
Belgium	15,22%	14,63%	-	-	-	-	15,22%	-	16,67%	<u>-</u>
Bulgaria	_	_	_	_	_	_	_	-	-	_
Croatia	2,17%	2,44%	_	_	_	_	2,17%	-	5,56%	_
Cyprus	_,		_	_	_	_		_		_
Czech Republic	2,17%	2,44%	_	_	_	_	2,17%	_	_	11,11%
Denmark	2,17%	2,44%	_	_	_	_	2,17%	_	5,56%	
Estonia	2,1770	2,4470	_	_	_	_	2,1770	_	3,3070	_
Finland	2,17%	2,44%	_	_	_	_	2,17%	-	5,56%	_
France	8,70%	7,32%	-	-	_	_	8,70%		5,50%	-
		14,63%	-	-	-	-	13,04%	-	16.670/	11 110/
Germany	13,04% 6,52%	7,32%	-	-	_	-	6,52%	-	16,67%	11,11% 11,11%
Greece			-	-	_	-		-	5,56%	
Hungary	2,17%	2,44%	-	-	-	-	2,17%	-	-	11,11%
Ireland	-	-	-	-	-	-	-	-		-
Italy	4,35%	4,88%	-	-	-	-	4,35%	-	5,56%	-
Latvia	-	-	-	-	-	-	-	-	-	-
Lithuania	-	-	-	-	-	-	-	-	-	-
Luxembourg	-	-	-	-	-	-	-	-	-	-
Malta	-	-	-	-	-	-	-	-	-	-
The Netherlands	-	-	-	-	-	-	-	-	-	-
Poland	2,17%	2,44%	-	-	-	-	2,17%	-	-	11,11%
Portugal	2,17%	2,44%	-	-	-	-	2,17%	-	-	11,11%
Romania	-	-	-	-	-	-	-	-	-	-
Slovakia	-	-	-	-	-	-	-	-	-	-
Slovenia	-	- 1	-	-	-	-	-	-	-	-
Spain	8,70%	4,88%	-	-	-	-	8,70%	-	-	22,22%
Sweden	2,17%	-	-	-	-	-	2,17%	-	5,56%	· -
United Kingdom	8,70%	9,76%	_	-	_	-	8,70%	-	16,67%	_
Other country	15,22%	17,07%	-	-	-	-	15,22%	-	16,67%	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	-	-	-	-	100,00%	-	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 8
In which country is the association you represent located?

Base = all associations

		Type of	law firm	Cor University/re	npany, Associa esearch institution	tion, on is located	С	ompanies by siz	e.	Position a	t company	Scope of activ	company vities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	46	-	-	-	-	-	-	-	-	-	-	-	-
Austria Belgium	2,17% 15,22%	-		- -	-			-	- -		-		
Bulgaria Croatia Cyprus	2,17%	- - -	- - -	- - -	- - -	- - -	-	- - -	-	- - -	-	-	-
Czech Republic Denmark	2,17% 2,17%		-			-	-	-	-	-			
Estonia Finland France	2,17% 8,70%	- - -	- - -	- -	- - -	- - -	-	- - -	-	- - -	-	-	-
Germany Greece	13,04% 6,52%	- -	- -	- -	- -	- -	- -		- -	- -	- -		
Hungary Ireland Italy	2,17% - 4,35%	-	-	- - -	- - -	- - -	- - -	- - -	- -	- - -	- - -	-	-
Latvia Lithuania	-	-	-	- -	-		-	- -	-	- -	-	-	-
Luxembourg Malta The Netherlands		-	-	- - -	- - -	- - -	- - -	- - -	-	- - -	- - -	-	-
Poland Portugal Romania	2,17% 2,17%		-	- -	- - -	-	-		-	-	- - -		-
Slovakia Slovenia		-	-	- -	- - -	- - -	-	- -	- -	-	- - -	-	-
Spain Sweden United Kingdom	8,70% 2,17% 8,70%	-	-	- - -	-	-	-	-	-	-	-	-	-
Other country	15,22%	-	-	-	-	-	-	-	-	-	-	-	-
No response Total	100,00%	-	-	- -	- -	- -	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Question 8 In which country is the association you represent located?

Base = all associations

	Total		itude towards SPC system		
		positiv	negativ		
Base	46	33	12		
Austria	2,17%	3,03%	-		
Belgium	15,22%	15,15%	16,67%		
Bulgaria	-	-	-		
Croatia	2,17%	3,03%	-		
Cyprus	-	-	-		
Czech Republic	2,17%	-	8,33%		
Denmark	2,17%	3,03%	-		
Estonia	-	-	-		
Finland	2,17%	3,03%	-		
France	8,70%	9,09%	8,33%		
Germany	13,04%	18,18%	-		
Greece	6,52%	6,06%	8,33%		
Hungary	2,17%	-	8,33%		
Ireland	-	-	-		
Italy	4,35%	3,03%	-		
Latvia	-	-	-		
Lithuania	-	-	-		
Luxembourg	-	-	-		
Malta	-	-	-		
The Netherlands	-	-	-		
Poland	2,17%	-	8,33%		
Portugal	2,17%	-	8,33%		
Romania	-	-	-		
Slovakia	-	-	-		
Slovenia	-	-	-		
Spain	8,70%	6,06%	16,67%		
Sweden	2,17%	3,03%	-		
United Kingdom	8,70%	12,12%	-		
Other country	15,22%	15,15%	16,67%		
No response	-	-	-		
Total	100,00%	100,00%	100,00%		

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 8
In which country is the association you represent located?

Base = all associations

		Total (without the			Type of st	akeholder			Representatives of		
	Total			Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic	2417	7.0000.00.00	institution	companies	companies	
Base	46	41	-	-	-	-	46	-	18	9	
Total EU 28	84,78%	82,93%	-	-	-	-	84,78%	-	83,33%	100,00%	
EZ 19	63,04%	60,98%	-	-	-	-	63,04%	-	50,00%	66,67%	
New Member States since 2004	8,70%	9,76%	-	-	-	-	8,70%	-	5,56%	33,33%	
Outside of the EU	15,22%	17,07%	-	-	-	-	15,22%	-	16,67%	-	
No response	-	-	-	-	-	-	-	-	-	-	

		Type of	law firm	Company, Association, University/research institution is located			С	companies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	46	-	-	-	-	-	-	-	-	-	-	-	-
Total EU 28	84,78%	-	-	-	-	-	-	-	-	-	-	-	-
EZ 19	63,04%	-	-	-	-	-	-	-	-	-	-	-	-
New Member States since 2004	8,70%	-	-	-	-	-	-	-	-	-	-	-	-
Outside of the EU	15,22%	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 8
In which country is the association you represent located?

Base = all associations

	Total	General attit current SF	ude towards C system
		positiv	negativ
Base	46	33	12
Total EU 28	84,78%	84,85%	83,33%
EZ 19	63,04%	63,64%	58,33%
New Member States since 2004	8,70%	3,03%	25,00%
Outside of the EU	15,22%	15,15%	16,67%
No response	-	-	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 9 How many members does your association have?

Base = all associations

		Total		Type of stakeholder					Representatives of		
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic	2417	7.0000.00.00	institution	companies	companies	
Base	46	41	-	-	=	-	46	=	18	9	
Below 50 members	36,96%	39,02%	-	-	-	-	36,96%	-	38,89%	77,78%	
50 upto 99 members	13,04%	12,20%	-	-	-	-	13,04%	-	27,78%	-	
100 upto 299 members	15,22%	17,07%	-	-	-	-	15,22%	-	22,22%	-	
300 members and more	34,78%	31,71%	-	-	-	-	34,78%	-	11,11%	22,22%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	-	-	-	-	100,00%	-	100,00%	100,00%	
Mean value	1362,17	1363,49	-	-	-	-	1362,17	-	180,06	103,56	

		Type of	law firm	Cor University/re	npany, Associa esearch institution	any, Association, arch institution is located Companies by size Position at company		Companies by size		t company	Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	46	-	-	-	-	-	-	-	-	-	-	-	-
Below 50 members	36,96%	-	-	-	-	-	-	-	-	-	-	-	-
50 upto 99 members	13,04%	-	-	-	-	-	-	-	-	-	-	-	-
100 upto 299 members	15,22%	-	-	-	-	-	-	-	-	-	-	-	-
300 members and more	34,78%	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	-	-	-	-	-	-	-	-	-	-
Mean value	1362,17	-	-	-	-	-	-	-	-	-	-	-	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 9 How many members does your association have?

Base = all associations

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	46	33	12
Below 50 members	36,96%	33,33%	50,00%
50 upto 99 members	13,04%	18,18%	-
100 upto 299 members	15,22%	12,12%	25,00%
300 members and more	34,78%	36,36%	25,00%
No response	-	-	-
Total	100,00%	100,00%	100,00%
Mean value	1362,17	1643,82	599,25

# Ouestion 10

Does your association mainly represent pharmaceutical companies or companies from the agrochemical sector?

### Base = all industry associations

		Total (without the			Type of st	akeholder			Represer	ntatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	33	30	-	-	-	-	33	-	18	9
Pharmaceutical companies	84,85%	83,33%	-	-	-	-	84,85%	-	100,00%	100,00%
Agrochemical companies	15,15%	16,67%	-	-	-	-	15,15%	-	-	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	-	-	-	-	100,00%	-	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			С	companies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	33	-	-	-	-	-	-	-	-	-	-	-	-
Pharmaceutical companies	84,85%	-	-	-	-	-	-	-	-	-	-	-	-
Agrochemical companies	15,15%	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Question 10

Does your association mainly represent pharmaceutical companies or companies from the agrochemical sector?

Base = all industry associations

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	33	26	7
Pharmaceutical companies Agrochemical companies	84,85% 15,15%	80,77% 19,23%	100,00%
No response	-	-	-
Total	100,00%	100,00%	100,00%

# Ouestion 11

Does your association mainly represent research-based companies ("originators") or generic companies?

Base = industry associations and "pharmaceutical companies" in Q10

		Total (without the				Represer	tatives of			
	Total	later accepted partici-		Company		Law firm Association		University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.00.00	institution	companies	companies
Base	28	25	-	-	-	-	28	-	18	9
Originators	64,29%	68,00%	-	-	-	-	64,29%	-	100,00%	-
Generic companies	32,14%	28,00%	-	-	-	-	32,14%	-	-	100,00%
No response	3,57%	4,00%	-	-	-	-	3,57%	-	-	-
Total	100,00%	100,00%	-	-	-	-	100,00%	-	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	28	-	-	-	-	-	-	-	-	-	-	-	-
Originators	64,29%	-	-	-	-	-	-	-	-	-	-	-	-
Generic companies	32,14%	-	-	-	-	-	-	-	-	-	-	-	-
No response	3,57%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Ouestion 11

Does your association mainly represent research-based companies ("originators") or generic companies?

Base = industry associations and "pharmaceutical companies" in Q10

	Total	General attitude toward current SPC system				
		positiv	negativ			
Base	28	21	7			
Originators	64,29%	85,71%	-			
Generic companies	32,14%	14,29%	85,71%			
No response	3,57%	-	14,29%			
Total	100,00%	100,00%	100,00%			

# Ouestion 12

Does your association mainly represent members of a particular industry, legal sector or academia?

### Base = all professional association

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		pants)	Total	Originator	Generic			institution	companies	companies	
Base	9	9	-	-	-	-	9	-	-	-	
Particular industry	22,22%	22,22%	-	-	-	-	22,22%	<u>-</u>	-	-	
Legal sector	77,78%	77,78%	-	-	-	-	77,78%	-	-	-	
Academia	-	-	-	-	-	-	-	-	-	-	
Other	-	-	-	_	-	-	-	-	-	-	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	-	-	-	-	100,00%	-	-	-	

		Type of	law firm	Con University/re	npany, Associat esearch institutio	tion, on is located	Companies by size			Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	9	-	-	-	-	-	-	-	-	-	-	-	-
Particular industry	22,22%	-	-	-	-	-	-	-	-	-	-	-	-
Legal sector	77,78%	-	-	-	-	-	-	-	-	-	-	-	-
Academia	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	_	-	_	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 12

Does your association mainly represent members of a particular industry, legal sector or academia?

Base = all professional association

	Total	General attit current SF	
		positiv	negativ
Base	9	5	3
Particular industry	22,22%	-	33,33%
Legal sector	77,78%	100,00%	66,67%
Academia	-	-	-
Other	-	-	-
No response	-	-	-
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 13 What type of law firm do you represent?

Base = all law firm or patent law firm

		Total (without the	Type of stakeholder						Representatives	
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	63	58	-	-	-	63	-	-	30	6
Global/international	33,33%	31,03%	-	-	-	33,33%	-	-	40,00%	16,67%
Regional (active in more than one country)	30,16%	31,03%	-	-	-	30,16%	-	-	30,00%	16,67%
National (office(s) in only one country)	33,33%	34,48%	-	-	-	33,33%	-	-	30,00%	66,67%
Local	1,59%	1,72%	-	-	-	1,59%	-	-	-	-
No response	1,59%	1,72%	-	-	-	1,59%	-	-	-	-
Total	100,00%	100,00%	-	-	-	100,00%	-	-	100,00%	100,00%
Global/international	33,33%	31,03%	_	_	_	33,33%	_	_	40,00%	16,67%
Regional/National/Local	65,08%	67,24%	-	-	-	65,08%	-	-	60,00%	83,33%

		Type of	law firm	Con University/re	npany, Associat esearch institution	ion, on is located	Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	63	21	41	-	-	-	-	-	-	-	-	-	-
Global/international	33,33%	100,00%	-	-	-	-	-	-	-	-	-	-	-
Regional (active in more than one country)	30,16%	-	46,34%	-	-	-	-	-	-	-	-	-	-
National (office(s) in only one country)	33,33%	-	51,22%	-	-	-	-	-	-	-	-	-	-
Local	1,59%	-	2,44%	-	-	-	-	-	-	-	-	-	-
No response	1,59%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-
Global/international	33,33%	100,00%	-	-	-	-	-	-	-	_	-	-	-
Regional/National/Local	65,08%	-	100,00%	-	-	-	-	-	-	-	-	-	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 13 What type of law firm do you represent?

Base = all law firm or patent law firm

	Total		ude towards PC system
		positiv	negativ
Base	63	41	22
Global/international	33,33%	41,46%	18,18%
Regional (active in more than one country)	30,16%	29,27%	31,82%
National (office(s) in only one country)	33,33%	24,39%	50,00%
Local	1,59%	2,44%	-
No response	1,59%	2,44%	-
Total	100,00%	100,00%	100,00%
Global/international	33,33%	41,46%	18,18%
Regional/National/Local	65,08%	56,10%	81,82%

# Ouestion 14

Does your law firm mainly represent research-based companies ("originators") or generic companies?

Base = all law firm or patent law firm

		Total (without the		Type of stakeholder						Representatives of		
	Total	later accepted		Company		. Law firm	Association	University/ Research	Originator	Generic		
		partici- pants)	Total	Originator	Generic			institution	companies	companies		
Base	63	58	-	-	-	63	-	-	30	6		
Originators	47,62%	44,83%	-	-	-	47,62%	-	-	100,00%	-		
Generic companies	9,52%	8,62%	-	-	-	9,52%	-	-	-	100,00%		
Impossible to say, it varies	42,86%	46,55%	-	-	-	42,86%	-	-	-	-		
No response	-	-	-	-	-	-	-	-	-	-		
Total	100,00%	100,00%	-	-	-	100,00%	-	-	100,00%	100,00%		

	Type of law firm Company, Association, University/research institution is located Companies by		ompanies by siz	nanies by size		t company	Scope of company activities						
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	63	21	41	-	-	-	-	-	-	-	-	-	-
Originators	47,62%	57,14%	43,90%	-	-	-	-	-	-	-	-	-	-
Generic companies	9,52%	4,76%	12,20%	-	-	-	-	-	-	-	-	-	-
Impossible to say, it varies	42,86%	38,10%	43,90%	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 14
Does your law firm mainly represent research-based companies ("originators") or generic companies?

Base = all law firm or patent law firm

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	63	41	22
Originators	47,62%	56,10%	31,82%
Generic companies	9,52%	4,88%	18,18%
Impossible to say, it varies	42,86%	39,02%	50,00%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Question 15
Does your law firm mainly represent right holders or competitors of right holders?

Base = all law firm or patent law firm

		Total		Type of stakeholder						ntatives of
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	63	58	-	-	-	63	-	-	30	6
Right holders	46,03%	46,55%	-	-	-	46,03%	-	-	76,67%	16,67%
Competitors of right holders	3,17%	1,72%	-	-	-	3,17%	-	-	-	33,33%
Impossible to say, it varies	49,21%	50,00%	-	-	-	49,21%	-	-	23,33%	50,00%
No response	1,59%	1,72%	-	-	-	1,59%	-	-	-	-
Total	100,00%	100,00%	-	-	-	100,00%	-	-	100,00%	100,00%

		Type of	law firm		npany, Associa esearch institution		Companies by size		Position a	Position at company		company vities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	63	21	41	-	-	-	-	-	-	-	-	-	-
Right holders	46,03%	52,38%	43,90%	-	-	-	-	-	-	-	-	-	-
Competitors of right holders	3,17%	4,76%	2,44%	-	-	-	-	-	-	-	-	-	-
Impossible to say, it varies	49,21%	38,10%	53,66%	-	-	-	-	-	-	-	-	-	-
No response	1,59%	4,76%	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 15
Does your law firm mainly represent right holders or competitors of right holders?

Base = all law firm or patent law firm

	Total	General attit current SF	
		positiv	negativ
Base	63	41	22
Right holders	46,03%	51,22%	36,36%
Competitors of right holders	3,17%	2,44%	4,55%
Impossible to say, it varies	49,21%	43,90%	59,09%
No response	1,59%	2,44%	-
Total	100,00%	100,00%	100,00%

Question 16
In which country is the university or research institution you represent located?

Base = all university or research institution

		Total (without the			Type of st	akeholder			Represer	ntatives of
	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic	Law mm	7100001411011	institution	companies	companies
Base	5	5	-	-	-	-	-	5	-	-
Austria	-	-	-	-	-	-	-	-	-	-
Belgium	-	-	-	-	-	-	-	-	-	-
Bulgaria	-	-	-	-	-	-	-	-	-	-
Croatia	-	-	-	-	-	-	-	-	-	-
Cyprus	-	-	-	-	-	-	-	-	-	-
Czech Republic	-	-	-	-	-	-	-	-	-	-
Denmark	-	-	-	-	-	-	-	-	-	-
Estonia	-	-	-	-	-	-	-	-	-	-
Finland	-	-	-	-	-	-	-	-	-	-
France	-	-	_	-	_	-	-	-	-	-
Germany	80,00%	80,00%	-	-	-	-	-	80,00%	-	-
Greece	-	-	-	-	_	-	-	-	-	-
Hungary	-	-	-	-	-	-	-	-	-	-
Ireland	-	-	-	-	-	-	-	-	-	-
Italy	-	-	-	-	-	-	-	-	-	-
Latvia	-	-	_	-	_	-	-	-	-	-
Lithuania	-	-	-	-	_	-	-	-	-	-
Luxembourg	-	-	-	-	-	-	-	-	-	_
Malta	_	-	-	-	_	-	-	-	-	-
The Netherlands	20,00%	20,00%	-	-	-	-	-	20,00%	-	-
Poland	-	-	-	-	_	-	-	-	-	-
Portugal	-	-	-	-	-	-	-	-	-	_
Romania	-	-	-	-	-	-	-	-	-	-
Slovakia	-	-	-	-	-	-	-	-	-	-
Slovenia	-	-	-	-	-	-	-	-	-	-
Spain	-	-	-	-	-	-	-	-	-	-
Sweden	-	-	-	-	-	-	-	-	-	-
United Kingdom	-	-	-	-	-	-	-	-	-	-
Other country	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	-	-	-	-	-	100,00%	-	-

Question 16 In which country is the university or research institution you represent located?

Base = all university or research institution

		Type of	law firm	Cor University/re	mpany, Associat esearch institutio	tion, on is located	С	ompanies by siz	e	Position a	t company	Scope of activ	company vities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	5	-	-	-	-	-	-	-	-	-	-	-	-
Austria Belgium Bulgaria Croatia Cyprus Czech Republic Denmark Estonia Finland France Germany Greece Hungary Ireland Italy Latvia	80,00%	- - - - - - - - - - - - - - - - - - -	-										
Lithuania Luxembourg Malta The Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom Other country	20,00% - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	- - - - - - - - - - - - - - - - - - -	-
Total	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 16 In which country is the university or research institution you represent located?

Base = all university or research institution

	Total		ude towards PC system
		positiv	negativ
Base	5	-	1
Austria	-	-	-
Belgium	-	-	-
Bulgaria	-	-	-
Croatia	-	-	-
Cyprus	-	-	-
Czech Republic	-	-	-
Denmark	-	-	-
Estonia	-	-	-
Finland	-	-	-
France	-	-	-
Germany	80,00%	-	100,00%
Greece	-	-	-
Hungary	-	-	-
Ireland	-	-	-
Italy	-	-	-
Latvia	-	-	-
Lithuania	-	-	-
Luxembourg	-	-	-
Malta The Netherlands	20.000/	-	-
Poland	20,00%	-	-
Polariu   Portugal	-	-	-
Romania	-	· -	_
Slovakia	_	_	
Slovenia	_	_	_
Spain	_	_	_
Sweden	_	_	_
United Kingdom	_	_	_
Other country	-	-	-
No response	-	-	-
Total	100,00%	-	100,00%

Question 16 In which country is the university or research institution you represent located?

# Base = all university or research institution

	Total (without the								Representatives of		
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici-	Total	Originator	Generic			institution	companies	companies	
Base	5	5	-	-	-	-	-	5	-	-	
Total EU 28	100,00%	100,00%	-	-	-	-	-	100,00%	-	-	
EZ 19	100,00%	100,00%	-	-	-	-	-	100,00%	-	-	
New Member States since 2004	-	-	-	-	-	-	-	-	-	-	
Outside of the EU	-	-	-	-	-	-	-	-	-	-	
No response	-	-	-	-	-	-	-	-	-	-	

		Type of	Type of law firm Com University/res			mpany, Association, esearch institution is located		ompanies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	5	-	-	-	-	-	-	-	-	-	-	-	-
Total EU 28	100,00%	-	-	-	-	-	-	-	-	-	-	-	-
EZ 19	100,00%	-	-	-	-	-	-	-	-	-	-	-	-
New Member States since 2004	-	-	-	-	-	-	-	-	-	-	-	-	-
Outside of the EU	-	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 16
In which country is the university or research institution you represent located?

Base = all university or research institution

	Total	General attit current SF		
		positiv	negativ	
Base	5	-	1	
Total EU 28	100,00%	-	100,00%	
EZ 19	100,00%	-	100,00%	
New Member States since 2004	-	-	-	
Outside of the EU	-	-	-	
No response	-	-	-	

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# Ouestion 17

Is the university or the research institution you represent involved in research and development activities in fields for which Supplementary Protection Certificate (SPC) protection is available?

Base = all university or research institution

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted partici-		Company		. Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	5	5	-	-	-	-	-	5	-	-	
Yes	40,00%	40,00%	-	-	-	-	-	40,00%	-	-	
No	60,00%	60,00%	-	-	-	-	-	60,00%	-	-	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	-	-	-	-	-	100,00%	-	-	

		Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	re	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	5	-	-	-	-	-	-	-	-	-	-	-	-
Yes	40,00%	-	-	-	-	-	-	-	-	-	-	-	-
No	60,00%	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 17

Is the university or the research institution you represent involved in research and development activities in fields for which Supplementary Protection Certificate (SPC) protection is available?

Base = all university or research institution

	Total	General attit current SF	
		positiv	negativ
Base	5	-	1
Yes	40,00%	-	100,00%
No	60,00%	-	-
No response	-	-	-
Total	100,00%	-	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 18

In the last ten years, has your company or university/research institution applied for authorisation to place a product on the European market before the European Medicines Agency (EMA) or the corresponding national authorities of any EU Member States? If you are not sure about the exact number, a rough estimate will suffice.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17)

	Total	Total (without the later accepted partici- pants)		Representatives of						
				Company		Law firm	Association	University/ Research institution	Originator companies	Generic companies
			Total	Originator	Generic					
Base	84	80	82	51	31	-	-	2	51	31
Below 50	38,10%	38,75%	39,02%	49,02%	22,58%	-	-	-	49,02%	22,58%
50 upto 199	19,05%	20,00%	19,51%	9,80%	35,48%	-	-	-	9,80%	35,48%
200 upto 499	4,76%	5,00%	4,88%	3,92%	6,45%	-	-	-	3,92%	6,45%
500 and more	11,90%	12,50%	12,20%	9,80%	16,13%	-	-	-	9,80%	16,13%
No, not during the last ten years	14,29%	13,75%	12,20%	15,69%	6,45%	-	-	100,00%	15,69%	6,45%
Don't know	5,95%	3,75%	6,10%	5,88%	6,45%	-	-	-	5,88%	6,45%
No response	5,95%	6,25%	6,10%	5,88%	6,45%	-	-	-	5,88%	6,45%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	100,00%
Mean value	172,53	175,33	172,53	149,11	207,20	-	-	-	149,11	207,20

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 18

In the last ten years, has your company or university/research institution applied for authorisation to place a product on the European market before the European Medicines Agency (EMA) or the corresponding national authorities of any EU Member States? If you are not sure about the exact number, a rough estimate will suffice.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17)

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	84	-	-	57	41	6	9	19	52	17	49	67	11
Below 50	38,10%	-	-	31,58%	34,15%	50,00%	11,11%	31,58%	48,08%	35,29%	46,94%	44,78%	9,09%
50 upto 199	19,05%	-	-	24,56%	24,39%	16,67%	33,33%	21,05%	17,31%	29,41%	16,33%	22,39%	9,09%
200 upto 499	4,76%	-	-	5,26%	4,88%	16,67%	11,11%	-	5,77%	5,88%	2,04%	5,97%	-
500 and more	11,90%	-	-	7,02%	4,88%	-	-	5,26%	15,38%	11,76%	10,20%	13,43%	-
No, not during the last ten years	14,29%	-	-	17,54%	17,07%	-	44,44%	26,32%	1,92%	17,65%	10,20%	5,97%	45,45%
Don't know	5,95%	-	-	5,26%	7,32%	-	-	10,53%	3,85%	-	10,20%	2,99%	18,18%
No response	5,95%	-	-	8,77%	7,32%	16,67%	-	5,26%	7,69%	-	4,08%	4,48%	18,18%
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Mean value	172,53	-	-	140,56	99,86	83,60	100,20	75,82	185,84	158,07	126,62	165,36	52,50

Institut für Demoskopie Allensbach

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

#### Ouestion 18

In the last ten years, has your company or university/research institution applied for authorisation to place a product on the European market before the European Medicines Agency (EMA) or the corresponding national authorities of any EU Member States? If you are not sure about the exact number, a rough estimate will suffice.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17)

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	84	50	32			
Below 50	38,10%	48,00%	25,00%			
50 upto 199	19,05%	14,00%	28,13%			
200 upto 499	4,76%	4,00%	6,25%			
500 and more	11,90%	10,00%	15,63%			
No, not during the last ten years	14,29%	16,00%	6,25%			
Don't know	5,95%	2,00%	12,50%			
No response	5,95%	6,00%	6,25%			
Total	100,00%	100,00%	100,00%			
Mean value	172,53	149,11	209,63			

In the last ten years, has your company or university/research institution applied for an SPC in Europe?

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17)

		Total (without the			Type of st	akeholder			Representatives of		
	Total late accept partic		Company			. Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	84	80	82	51	31	-	-	2	51	31	
Yes, several times	46,43%	46,25%	47,56%	72,55%	6,45%	-	-	-	72,55%	6,45%	
Yes, only once	5,95%	6,25%	6,10%	3,92%	9,68%	-	-	-	3,92%	9,68%	
No, never	45,24%	46,25%	43,90%	23,53%	77,42%	-	-	100,00%	23,53%	77,42%	
Don't know	2,38%	1,25%	2,44%	-	6,45%	-	-	-	-	6,45%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	100,00%	

	Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	84	-	-	57	41	6	9	19	52	17	49	67	11
Yes, several times	46,43%	-	-	29,82%	26,83%	-	-	10,53%	69,23%	47,06%	42,86%	56,72%	-
Yes, only once	5,95%	-	-	8,77%	9,76%	16,67%	11,11%	5,26%	5,77%	5,88%	8,16%	7,46%	-
No, never	45,24%	-	-	59,65%	60,98%	83,33%	88,89%	78,95%	25,00%	47,06%	44,90%	34,33%	100,00%
Don't know	2,38%	-	-	1,75%	2,44%	-	-	5,26%	-	-	4,08%	1,49%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Base: SPC Stakeholders

Institut für Demoskopie Allensbach

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

### Ouestion 19

In the last ten years, has your company or university/research institution applied for an SPC in Europe?

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17)

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	84	50	32
Yes, several times	46,43%	66,00%	18,75%
Yes, only once	5,95%	6,00%	6,25%
No, never	45,24%	26,00%	71,88%
Don't know	2,38%	2,00%	3,13%
No response	-	-	-
Total	100,00%	100,00%	100,00%

## Question 20

Did your company or university/research institution ever obtain such an SPC?

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

		Total (without the				Representatives of				
	Total	later accepted partici-		Company		. Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
Yes	97,73%	97,62%	97,73%	100,00%	80,00%	-	-	-	100,00%	80,00%
No	2,27%	2,38%	2,27%	-	20,00%	-	-	-	-	20,00%
Don't know	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			C	ompanies by siz	ze .	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
Yes	97,73%	-	-	95,45%	100,00%	-	100,00%	100,00%	97,44%	100,00%	96,00%	97,67%	-
No	2,27%	-	-	4,55%	-	100,00%	-	-	2,56%	-	4,00%	2,33%	-
Don't know	-	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 20

Question 20
Did your company or university/research institution ever obtain such an SPC?

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

	Total	General attit current SF	
		positiv	negativ
Base	44	36	8
Yes	97,73%	100,00%	87,50%
No	2,27%	-	12,50%
Don't know	-	-	-
No response	-	-	-
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Base: SPC Stakeholders

On average, in how many EU Member States do you apply for SPCs? If you're not sure about the exact number, a rough estimate will suffice.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

		Total (without the			Type of st	akeholder			Represer	tatives of
	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
In all EU member states (28)	40,91%	40,48%	40,91%	41,03%	40,00%	- -	-	-	41,03%	40,00%
In less than 28 member states	40,91%	42,86%	40,91%	43,59%	20,00%	-	-	-	43,59%	20,00%
Impossible to say, it varies	18,18%	16,67%	18,18%	15,38%	40,00%	-	-	-	15,38%	40,00%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Mean value	23,86	23,74	23,86	23,88	23,67	-	-	-	23,88	23,67

		Type of law firm			Company, Association, University/research institution is located			ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
In all EU member states (28)	40,91%	-	-	36,36%	26,67%	100,00%	-	-	46,15%	22,22%	40,00%	41,86%	-
In less than 28 member states	40,91%	-	-	50,00%	60,00%	-	100,00%	100,00%	33,33%	33,33%	48,00%	39,53%	-
Impossible to say, it varies	18,18%	-	-	13,64%	13,33%	-	-	-	20,51%	44,44%	12,00%	18,60%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-
Mean value	23,86	-	-	23,32	21,69	28,00	16,00	20,00	24,61	21,40	23,27	23,97	-

On average, in how many EU Member States do you apply for SPCs? If you're not sure about the exact number, a rough estimate will suffice.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	44	36	8			
In all EU member states (28)	40,91%	41,67%	37,50%			
In less than 28 member states	40,91%	41,67%	37,50%			
Impossible to say, it varies	18,18%	16,67%	25,00%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Mean value	23,86	23,93	23,50			

Is the geographical coverage of your SPC applications generally the same as the geographical coverage of the basic patent or is it smaller?

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

		Total (without the			Type of st	akeholder			Representatives of		
	Total lat		Company			Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies	
Base	44	42	44	39	5	-	-	-	39	5	
The same	86,36%	85,71%	86,36%	87,18%	80,00%	-	-	-	87,18%	80,00%	
Smaller than the basic patent	11,36%	11,90%	11,36%	12,82%	-	-	-	-	12,82%	-	
Impossible to say, it varies	2,27%	2,38%	2,27%	-	20,00%	-	-	-	-	20,00%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%	

		Type of law firm		Con University/re	npany, Associat search institution	tion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
The same	86,36%	-	-	81,82%	73,33%	100,00%	-	100,00%	87,18%	88,89%	80,00%	86,05%	-
Smaller than the basic patent	11,36%	-	-	13,64%	20,00%	-	100,00%	-	10,26%	11,11%	16,00%	11,63%	-
Impossible to say, it varies	2,27%	-	-	4,55%	6,67%	-	-	-	2,56%	-	4,00%	2,33%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-

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### Ouestion 22

Is the geographical coverage of your SPC applications generally the same as the geographical coverage of the basic patent or is it smaller?

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	44	36	8			
The same	86,36%	91,67%	62,50%			
Smaller than the basic patent	11,36%	8,33%	25,00%			
Impossible to say, it varies	2,27%	-	12,50%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

### Question 23

Now thinking specifically about cases where your company or university/research institution applies for an SPC and markets pharmaceutical products:

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

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

		Total			Type of st	akeholder			Represer	tatives of
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
Always	27,27%	28,57%	27,27%	30,77%	-	-	-	-	30,77%	-
In most cases	65,91%	64,29%	65,91%	61,54%	100,00%	-	-	-	61,54%	100,00%
Rarely	2,27%	2,38%	2,27%	2,56%	-	-	-	-	2,56%	-
Never	-	-	-	-	-	-	-	-	-	-
Impossible to say, it varies	2,27%	2,38%	2,27%	2,56%	-	-	-	-	2,56%	-
No response	2,27%	2,38%	2,27%	2,56%	-	-	-	-	2,56%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Always, In most cases	93,18%	92,86%	93,18%	92,31%	100,00%	-	-	-	92,31%	100,00%
Rarely, Never	2,27%	2,38%	2,27%	2,56%	-	-	-	-	2,56%	-

		Type of	law firm	Con University/re	npany, Associat esearch institution	tion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
Always	27,27%	-	-	22,73%	20,00%	-	-	33,33%	25,64%	11,11%	32,00%	25,58%	-
In most cases	65,91%	-	-	68,18%	80,00%	100,00%	100,00%	66,67%	66,67%	88,89%	64,00%	67,44%	-
Rarely	2,27%	-	-	-	-	-	-	-	2,56%	-	4,00%	2,33%	-
Never	-	-	-	-	-	-	-	-	-	-	-	-	-
Impossible to say, it varies	2,27%	-	-	4,55%	-	-	-	-	2,56%	-	-	2,33%	-
No response	2,27%	-	-	4,55%	-	-	-	-	2,56%	-	-	2,33%	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-
Always, In most cases	93,18%	-	-	90,91%	100,00%	100,00%	100,00%	100,00%	92,31%	100,00%	96,00%	93,02%	-
Rarely, Never	2,27%	-	-	-	-	-	-	-	2,56%	-	4,00%	2,33%	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Base: SPC Stakeholders

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Ouestion 23

Now thinking specifically about cases where your company or university/research institution applies for an SPC and markets pharmaceutical products:

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

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	44	36	8			
Always	27,27%	27,78%	25,00%			
In most cases	65,91%	63,89%	75,00%			
Rarely	2,27%	2,78%	-			
Never	-	-	-			
Impossible to say, it varies	2,27%	2,78%	-			
No response	2,27%	2,78%	-			
Total	100,00%	100,00%	100,00%			
Always, In most cases	93,18%	91,67%	100,00%			
Rarely, Never	2,27%	2,78%	-			

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

1) We conduct freedom to operate searches on granted patents or patent applications in the preparation stage of research projects.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

1) We conduct freedom to		Total (without the			Type of st	akeholder			Represen	tatives of
operate searches on granted patents or patent applications in the preparation stage of	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
research projects.		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
Always	29,55%	30,95%	29,55%	20,51%	100,00%	-	-	-	20,51%	100,00%
In most cases	65,91%	64,29%	65,91%	74,36%	-	-	-	-	74,36%	-
Now and then	-	-	-	-	-	-	-	-	-	-
Never	-	-	-	-	-	-	-	-	-	-
Don't know	4,55%	4,76%	4,55%	5,13%	-	-	-	-	5,13%	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Always, In most cases  Now and then, Never	95,45% -	95,24% -	95,45%	94,87%	100,00%	-	-	-	94,87%	100,00%

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

1) We conduct freedom to operate searches on granted patents or patent applications in the preparation stage of research projects.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

We conduct freedom to	Type of law firm			Company, Association, University/research institution is located			C	ompanies by siz	ze	Position a	t company	Scope of company activities	
operate searches on granted patents or patent applications in the preparation stage of research projects.	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
Always	29,55%	-	-	40,91%	40,00%	100,00%	100,00%	66,67%	25,64%	22,22%	28,00%	30,23%	-
In most cases	65,91%	-	-	54,55%	60,00%	-	-	33,33%	69,23%	77,78%	64,00%	65,12%	-
Now and then	-	-	-	-	-	-	-	-	-	-	-	-	-
Never	-	-	-	-	-	-	-	-	-	-	-	-	-
Don't know	4,55%	-	-	4,55%	-	-	-	-	5,13%	-	8,00%	4,65%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-
Always, In most cases Now and then, Never	95,45% -	-	-	95,45% -	100,00%	100,00%	100,00%	100,00%	94,87%	100,00%	92,00%	95,35% -	

#### Question 24

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

1) We conduct freedom to operate searches on granted patents or patent applications in the preparation stage of research projects.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

We conduct freedom to operate searches on granted patents or patent applications in	Total		ude towards PC system
the preparation stage of research projects.		positiv	negativ
Base	44	36	8
Always	29,55%	22,22%	62,50%
In most cases	65,91%	72,22%	37,50%
Now and then	-	-	-
Never	-	-	-
Don't know	4,55%	5,56%	-
No response	-	-	-
Total	100,00%	100,00%	100,00%
Always, In most cases Now and then, Never	95,45%	94,44%	100,00%

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

2) We conduct freedom to operate searches on granted SPCs or SPC applications in the preparation stage of research projects.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

2) We conduct freedom to		Total (without the			Type of st	akeholder			Represen	tatives of
operate searches on granted SPCs or SPC applications in the preparation stage of research	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
projects.		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
Always	20,45%	21,43%	20,45%	10,26%	100,00%	-	-	-	10,26%	100,00%
In most cases	13,64%	11,90%	13,64%	15,38%	-	-	-	-	15,38%	-
Now and then	52,27%	54,76%	52,27%	58,97%	-	-	-	-	58,97%	-
Never	6,82%	4,76%	6,82%	7,69%	-	-	-	-	7,69%	-
Don't know	6,82%	7,14%	6,82%	7,69%	-	-	-	-	7,69%	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Always, In most cases	34,09%	33,33%	34,09%	25,64%	100,00%	-	-	-	25,64%	100,00%
Now and then, Never	59,09%	59,52%	59,09%	66,67%	-	-	-	-	66,67%	-

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

2) We conduct freedom to operate searches on granted SPCs or SPC applications in the preparation stage of research projects.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

2) We conduct freedom to	Type of law firm			Company, Association, University/research institution is located			C	ompanies by siz	e	Position at	t company	Scope of company activities	
operate searches on granted SPCs or SPC applications in the preparation stage of research projects.	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
Always	20,45%	-	-	27,27%	26,67%	100,00%	-	66,67%	17,95%	11,11%	24,00%	20,93%	-
In most cases	13,64%	-	-	13,64%	20,00%	-	-	33,33%	12,82%	11,11%	20,00%	13,95%	-
Now and then	52,27%	-	-	50,00%	46,67%	-	-	-	56,41%	55,56%	40,00%	51,16%	-
Never	6,82%	-	-	4,55%	6,67%	-	100,00%	-	5,13%	11,11%	8,00%	6,98%	-
Don't know	6,82%	-	-	4,55%	-	-	-	-	7,69%	11,11%	8,00%	6,98%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-
Always, In most cases	34,09%	-	-	40,91%	46,67%	100,00%	-	100,00%	30,77%	22,22%	44,00%	34,88%	-
Now and then, Never	59,09%	-	-	54,55%	53,33%	-	100,00%	-	61,54%	66,67%	48,00%	58,14%	-

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

2) We conduct freedom to operate searches on granted SPCs or SPC applications in the preparation stage of research projects.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

We conduct freedom to operate searches on granted SPCs or SPC applications in the	Total	General attitude towards current SPC system				
preparation stage of research projects.		positiv	negativ			
Base	44	36	8			
Always	20,45%	11,11%	62,50%			
In most cases	13,64%	13,89%	12,50%			
Now and then	52,27%	61,11%	12,50%			
Never	6,82%	5,56%	12,50%			
Don't know	6,82%	8,33%	-			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Always, In most cases	34,09%	25,00%	75,00%			
Now and then, Never	59,09%	66,67%	25,00%			

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

3) We consult patent applications or patents as a source of information for our research before we start or when we are completing a research project.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

3) We consult patent		Total (without the			Type of st	akeholder			Represer	tatives of
applications or patents as a source of information for our research before we start or when we are completing a	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
research project.		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
Always	18,18%	19,05%	18,18%	15,38%	40,00%	-	-	-	15,38%	40,00%
In most cases	70,45%	71,43%	70,45%	74,36%	40,00%	-	-	-	74,36%	40,00%
Now and then	9,09%	7,14%	9,09%	7,69%	20,00%	-	-	-	7,69%	20,00%
Never	-	-	-	-	-	-	-	-	-	-
Don't know	2,27%	2,38%	2,27%	2,56%	-	-	-	-	2,56%	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Always, In most cases	88,64%	90,48%	88,64%	89,74%	80,00%	-	-	-	89,74%	80,00%
Now and then, Never	9,09%	7,14%	9,09%	7,69%	20,00%	-	-	-	7,69%	20,00%

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

3) We consult patent applications or patents as a source of information for our research before we start or when we are completing a research project.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

3) We consult patent		Type of law firm		Company, Association, University/research institution is located			C	ompanies by siz	re	Position a	t company	Scope of company activities	
applications or patents as a source of information for our research before we start or when we are completing a research project.	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
Always	18,18%	-	-	27,27%	40,00%	-	100,00%	66,67%	12,82%	22,22%	20,00%	18,60%	-
In most cases	70,45%	-	-	59,09%	46,67%	100,00%	-	-	76,92%	66,67%	64,00%	69,77%	-
Now and then	9,09%	-	-	9,09%	6,67%	-	-	33,33%	7,69%	11,11%	12,00%	9,30%	-
Never	-	-	-	-	-	-	-	-	-	-	-	-	-
Don't know	2,27%	-	-	4,55%	6,67%	-	-	-	2,56%	-	4,00%	2,33%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-
Always, In most cases	88,64%	-	-	86,36%	86,67%	100,00%	100,00%	66,67%	89,74%	88,89%	84,00%	88,37%	-
Now and then, Never	9,09%	-	-	9,09%	6,67%	-	-	33,33%	7,69%	11,11%	12,00%	9,30%	-

#### Question 24

How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

3) We consult patent applications or patents as a source of information for our research before we start or when we are completing a research project.

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

We consult patent applications or patents as a source of information for our research before we start or	Total	General attitude towards current SPC system				
when we are completing a research project.		positiv	negativ			
Base	44	36	8			
Always	18,18%	19,44%	12,50%			
In most cases	70,45%	77,78%	37,50%			
Now and then	9,09%	-	50,00%			
Never	-	-	-			
Don't know	2,27%	2,78%	-			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Always, In most cases	88,64%	97,22%	50,00%			
Now and then, Never	9,09%	- 50,00%				

Question 25
Which of the following statements apply if your research objectives involve testing whether molecules or biological substances fulfill specific intended purposes? (Multiple responses possible)

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

		Total			Type of st	akeholder			Represer	ntatives of
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	44	42	44	39	5	-	-	-	39	5
We manufacture the molecules or compounds that we need for our research activity ourselves	88,64%	90,48%	88,64%	89,74%	80,00%	-	-	-	89,74%	80,00%
We employ specific suppliers who manufacture the molecules or compounds or isolate the biological material	81,82%	83,33%	81,82%	82,05%	80,00%	-	-	-	82,05%	80,00%
We buy the compounds on the market without specifically employing a manufacturer.	70,45%	69,05%	70,45%	69,23%	80,00%	-	-	-	69,23%	80,00%
Sum of answers	240,91%	242,86%	240,91%	241,03%	240,00%	-	-	-	241,03%	240,00%
No response	4,55%	4,76%	4,55%	2,56%	20,00%	-	-	-	2,56%	20,00%

		Type of	law firm	Con University/re	npany, Associat esearch institutio	ion, on is located	C	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	44	-	-	22	15	1	1	3	39	9	25	43	-
We manufacture the molecules or compounds that we need for our research activity ourselves	88,64%	-	-	90,91%	93,33%	100,00%	100,00%	66,67%	89,74%	77,78%	88,00%	88,37%	-
We employ specific suppliers who manufacture the molecules or compounds or isolate the biological material	81,82%	-	-	81,82%	73,33%	100,00%	100,00%	66,67%	82,05%	77,78%	80,00%	81,40%	-
We buy the compounds on the market without specifically employing a manufacturer.	70,45%	-	-	68,18%	60,00%	100,00%	-	66,67%	74,36%	55,56%	76,00%	72,09%	-
Sum of answers	240,91%	-	-	240,91%	226,67%	300,00%	200,00%	200,00%	246,15%	211,11%	244,00%	241,86%	-
No response	4,55%	-	-	-	-	-	-	-	5,13%	22,22%	-	4,65%	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Base: SPC Stakeholders

Institut für Demoskopie Allensbach

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 25
Which of the following statements apply if your research objectives involve testing whether molecules or biological substances fulfill specific intended purposes? (Multiple responses possible)

Base = all companies and universities/research institutions active in any SPC field (according to Q3 and Q17) and "yes" in Q19

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	44	36	8			
We manufacture the molecules or compounds that we need for our research activity ourselves	88,64%	94,44%	62,50%			
We employ specific suppliers who manufacture the molecules or compounds or isolate the biological material	81,82%	88,89%	50,00%			
We buy the compounds on the market without specifically employing a manufacturer.	70,45%	72,22%	62,50%			
Sum of answers	240,91%	255,56%	175,00%			
No response	4,55%	2,78%	12,50%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Base: SPC Stakeholders

Please indicate the extent to which you agree or disagree with each of the following statements:

# 1) The current SPC Regulations on medicinal and plant protection products (Regulation 469/2009/EC and Regulation 1610/96/EC) effectively prevent research centres situated in EU Member States from relocating to countries outside the EU

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

The current SPC Regulations on medicinal and plant					Type of st	akeholder				
protection products (Regulation 469/2009/EC and Regulation	Total.	Total (without the later		Company					Represer	ntatives of
1610/96/EC) effectively prevent research centres situated in EU Member States from relocating to countries outside the EU	Total	accepted partici- pants)	Total	Originator	Generic	Law firm	Association	University/ Research institution	Originator companies	Generic companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	12,44%	12,85%	19,51%	29,41%	3,23%	-	17,39%	-	20,20%	6,52%
Agree	23,32%	24,02%	23,17%	27,45%	16,13%	23,81%	23,91%	-	31,31%	17,39%
Disagree	22,28%	21,23%	25,61%	17,65%	38,71%	19,05%	19,57%	50,00%	17,17%	36,96%
Strongly disagree	11,40%	11,17%	9,76%	5,88%	16,13%	17,46%	6,52%	-	6,06%	15,22%
Impossible to say	30,57%	30,73%	21,95%	19,61%	25,81%	39,68%	32,61%	50,00%	25,25%	23,91%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	35,75%	36,87%	42,68%	56,86%	19,35%	23,81%	41,30%	-	51,52%	23,91%
Disagree, Strongly disagree	33,68%	32,40%	35,37%	23,53%	54,84%	36,51%	26,09%	50,00%	23,23%	52,17%

Please indicate the extent to which you agree or disagree with each of the following statements:

# 1) The current SPC Regulations on medicinal and plant protection products (Regulation 469/2009/EC and Regulation 1610/96/EC) effectively prevent research centres situated in EU Member States from relocating to countries outside the EU

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

The current SPC Regulations on medicinal and plant protection products (Regulation products)		Type of	law firm	Company, Association, University/research institution is located			Co	ompanies by siz	e	Position a	t company	Scope of company activities	
469/2009/EC and Regulation 1610/96/EC) effectively prevent research centres situated in EU Member States from relocating to countries outside the EU	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	12,44%	-	-	12,28%	12,20%	-	-	-	28,85%	29,41%	8,16%	20,90%	9,09%
Agree	23,32%	38,10%	17,07%	21,05%	17,07%	16,67%	11,11%	10,53%	30,77%	11,76%	26,53%	25,37%	18,18%
Disagree	22,28%	9,52%	21,95%	29,82%	34,15%	33,33%	55,56%	36,84%	15,38%	23,53%	32,65%	23,88%	27,27%
Strongly disagree	11,40%	28,57%	12,20%	14,04%	12,20%	33,33%	11,11%	5,26%	11,54%	17,65%	8,16%	8,96%	18,18%
Impossible to say	30,57%	23,81%	48,78%	22,81%	24,39%	16,67%	22,22%	47,37%	13,46%	17,65%	24,49%	20,90%	27,27%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strangly and Asses	05.750/	20.100/	47.070/	22.2224	20.2704	10.070/	11 110/	10 500/	E0.000/	44.4007	04.000/	40.0704	27.270/
Strongly agree, Agree	35,75%	38,10%	17,07%	33,33%	29,27%	16,67%	11,11%	10,53%	59,62%	41,18%	34,69%	46,27%	27,27%
Disagree, Strongly disagree	33,68%	38,10%	34,15%	43,86%	46,34%	66,67%	66,67%	42,11%	26,92%	41,18%	40,82%	32,84%	45,45%

Please indicate the extent to which you agree or disagree with each of the following statements:

1) The current SPC Regulations on medicinal and plant protection products (Regulation 469/2009/EC and Regulation 1610/96/EC) effectively prevent research centres situated in EU Member States from relocating to countries outside the EU

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

1) The current SPC Regulations on medicinal and plant protection products (Regulation 469/2009/EC and Regulation 1610/96/EC) effectively prevent research centres situated in EU Member	Total		ude towards PC system			
States from relocating to countries outside the EU		positiv negativ				
Base	193	124	66			
Strongly agree	12,44%	17,74%	3,03%			
Agree	23,32%	29,84%	12,12%			
Disagree	22,28%	15,32%	36,36%			
Strongly disagree	11,40%	10,48%	13,64%			
Impossible to say	30,57%	26,61%	34,85%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	35,75%	47,58%	15,15%			
Disagree, Strongly disagree	33,68%	25,81%	50,00%			

Please indicate the extent to which you agree or disagree with each of the following statements:

2) The SPC system as currently practised encourages European manufacturers of generic medicines to relocate production facilities to countries outside the EU

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

2) The SPC system as currently		Total (without the			Type of st	akeholder			Represen	tatives of
practised encourages European manufacturers of generic medicines to relocate production facilities to countries outside the	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
EU		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	17,62%	17,32%	28,05%	9,80%	58,06%	4,76%	17,39%	-	8,08%	52,17%
Agree	20,21%	21,23%	17,07%	7,84%	32,26%	34,92%	6,52%	-	11,11%	34,78%
Disagree	23,32%	22,91%	21,95%	33,33%	3,23%	23,81%	23,91%	50,00%	29,29%	4,35%
Strongly disagree	17,62%	17,32%	20,73%	33,33%	-	11,11%	21,74%	-	28,28%	2,17%
Impossible to say	21,24%	21,23%	12,20%	15,69%	6,45%	25,40%	30,43%	50,00%	23,23%	6,52%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	37,82%	38,55%	45,12%	17,65%	90,32%	39,68%	23,91%	-	19,19%	86,96%
Disagree, Strongly disagree	40,93%	40,22%	42,68%	66,67%	3,23%	34,92%	45,65%	50,00%	57,58%	6,52%

Please indicate the extent to which you agree or disagree with each of the following statements:

# 2) The SPC system as currently practised encourages European manufacturers of generic medicines to relocate production facilities to countries outside the EU

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

2) The SPC system as currently	2) The SPC system as currently practised encourages European				npany, Associat esearch institution		C	ompanies by siz	е	Position a	t company	Scope of company activities	
manufacturers of generic medicines to relocate production facilities to countries outside the EU	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	17,62%	9,52%	2,44%	35,09%	29,27%	100,00%	33,33%	31,58%	23,08%	35,29%	24,49%	26,87%	27,27%
Agree	20,21%	28,57%	36,59%	19,30%	24,39%	-	22,22%	36,84%	9,62%	11,76%	20,41%	14,93%	36,36%
Disagree	23,32%	28,57%	21,95%	19,30%	19,51%	-	22,22%	10,53%	26,92%	23,53%	22,45%	25,37%	-
Strongly disagree	17,62%	14,29%	9,76%	15,79%	14,63%	-	11,11%	-	30,77%	23,53%	18,37%	22,39%	18,18%
Impossible to say	21,24%	19,05%	29,27%	10,53%	12,20%	-	11,11%	21,05%	9,62%	5,88%	14,29%	10,45%	18,18%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	37,82%	38,10%	39,02%	54,39%	53,66%	100,00%	55,56%	68,42%	32,69%	47,06%	44,90%	41,79%	63,64%
Disagree, Strongly disagree	40,93%	42,86%	31,71%	35,09%	34,15%	-	33,33%	10,53%	57,69%	47,06%	40,82%	47,76%	18,18%

Please indicate the extent to which you agree or disagree with each of the following statements:

2) The SPC system as currently practised encourages European manufacturers of generic medicines to relocate production facilities to countries outside the EU

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

2) The SPC system as currently practised encourages European manufacturers of generic medicines to relocate production	Total	General attitude towards current SPC system				
facilities to countries outside the EU		positiv	negativ			
Base	193	124	66			
Strongly agree	17,62%	7,26%	37,88%			
Agree	20,21%	14,52%	31,82%			
Disagree	23,32%	26,61%	16,67%			
Strongly disagree	17,62%	26,61%	1,52%			
Impossible to say	21,24%	25,00%	12,12%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	37,82%	21,77%	69,70%			
Disagree, Strongly disagree	40,93%	53,23% 18,18%				

Please indicate the extent to which you agree or disagree with each of the following statements:

# 3) The current SPC regime takes all the involved interests sufficiently into account

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Represer	tatives of
The current SPC regime takes all the involved interests sufficiently into account	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
-		partici- pants)	Total	Total Originator Generic				institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	26,42%	26,82%	32,93%	52,94%	-	11,11%	36,96%	-	45,45%	4,35%
Agree	29,53%	30,17%	19,51%	23,53%	12,90%	46,03%	26,09%	-	30,30%	15,22%
Disagree	24,35%	25,14%	29,27%	17,65%	48,39%	25,40%	13,04%	50,00%	17,17%	43,48%
Strongly disagree	12,44%	10,61%	15,85%	3,92%	35,48%	7,94%	13,04%	-	4,04%	34,78%
Impossible to say	7,25%	7,26%	2,44%	1,96%	3,23%	9,52%	10,87%	50,00%	3,03%	2,17%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	55,96%	56,98%	52,44%	76,47%	12,90%	57,14%	63,04%	-	75,76%	19,57%
Disagree, Strongly disagree	36,79%	35,75%	45,12%	21,57%	83,87%	33,33%	26,09%	50,00%	21,21%	78,26%

Please indicate the extent to which you agree or disagree with each of the following statements:

# 3) The current SPC regime takes all the involved interests sufficiently into account

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	3) The current SPC regime			Company, Association, University/research institution is located			C	ompanies by siz	ze	Position a	t company	Scope of company activities	
The current SPC regime takes all the involved interests sufficiently into account	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	26,42%	23,81%	4,88%	21,05%	17,07%	-	-	-	51,92%	35,29%	28,57%	38,81%	9,09%
Agree	29,53%	52,38%	41,46%	22,81%	26,83%	-	66,67%	21,05%	9,62%	35,29%	12,24%	16,42%	18,18%
Disagree	24,35%	4,76%	36,59%	31,58%	29,27%	50,00%	33,33%	36,84%	26,92%	17,65%	34,69%	28,36%	45,45%
Strongly disagree	12,44%	14,29%	4,88%	21,05%	21,95%	50,00%	-	31,58%	11,54%	11,76%	20,41%	14,93%	18,18%
Impossible to say	7,25%	4,76%	12,20%	3,51%	4,88%	-	-	10,53%	-	-	4,08%	1,49%	9,09%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	55,96%	76,19%	46,34%	43,86%	43,90%	-	66,67%	21,05%	61,54%	70,59%	40,82%	55,22%	27,27%
Disagree, Strongly disagree	36,79%	19,05%	41,46%	52,63%	51,22%	100,00%	33,33%	68,42%	38,46%	29,41%	55,10%	43,28%	63,64%

Please indicate the extent to which you agree or disagree with each of the following statements:

# 3) The current SPC regime takes all the involved interests sufficiently into account

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

The current SPC regime takes all the involved interests	Total	General attitude towards current SPC system				
sufficiently into account		positiv	negativ			
Base	193	124	66			
Strongly agree	26,42%	41,13%	-			
Agree	29,53%	45,97%	-			
Disagree	24,35%	6,45%	59,09%			
Strongly disagree	12,44%	1,61%	33,33%			
Impossible to say	7,25%	4,84%	7,58%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	55,96%	87,10%	-			
Disagree, Strongly disagree	36,79%	8,06%	92,42%			

Please indicate the extent to which you agree or disagree with each of the following statements:

# 4) The current SPC regime fosters the investment in research and development (R&D) activities

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

4) The current SPC regime fosters the investment in research and development		Total				Representatives of					
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
(R&D) activities		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Strongly agree	38,34%	38,55%	43,90%	68,63%	3,23%	22,22%	50,00%	50,00%	59,60%	6,52%	
Agree	41,97%	43,58%	30,49%	15,69%	54,84%	68,25%	28,26%	-	28,28%	56,52%	
Disagree	12,95%	12,29%	17,07%	9,80%	29,03%	7,94%	13,04%	-	9,09%	21,74%	
Strongly disagree	2,07%	1,68%	3,66%	1,96%	6,45%	1,59%	-	-	1,01%	6,52%	
Impossible to say	4,66%	3,91%	4,88%	3,92%	6,45%	-	8,70%	50,00%	2,02%	8,70%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	
Strongly agree, Agree	80,31%	82,12%	74,39%	84,31%	58,06%	90,48%	78,26%	50,00%	87,88%	63,04%	
Disagree, Strongly disagree	15,03%	13,97%	20,73%	11,76%	35,48%	9,52%	13,04%	-	10,10%	28,26%	

Please indicate the extent to which you agree or disagree with each of the following statements:

# 4) The current SPC regime fosters the investment in research and development (R&D) activities

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

4) The current SPC regime	Type of law firm		Company, Association, University/research institution is located			Co	ompanies by siz	е	Position at company		Scope of company activities		
fosters the investment in research and development (R&D) activities	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	38,34%	38,10%	14,63%	35,09%	36,59%	-	33,33%	5,26%	61,54%	41,18%	40,82%	49,25%	18,18%
Agree	41,97%	52,38%	75,61%	38,60%	36,59%	33,33%	44,44%	57,89%	19,23%	35,29%	34,69%	29,85%	45,45%
Disagree	12,95%	4,76%	9,76%	15,79%	17,07%	50,00%	11,11%	15,79%	15,38%	17,65%	16,33%	13,43%	18,18%
Strongly disagree	2,07%	4,76%	-	3,51%	2,44%	16,67%	-	5,26%	3,85%	5,88%	2,04%	2,99%	9,09%
Impossible to say	4,66%	-	-	7,02%	7,32%	-	11,11%	15,79%	-	-	6,12%	4,48%	9,09%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	80,31%	90,48%	90,24%	73,68%	73,17%	33,33%	77,78%	63,16%	80,77%	76,47%	75,51%	79,10%	63,64%
Disagree, Strongly disagree	15,03%	9,52%	9,76%	19,30%	19,51%	66,67%	11,11%	21,05%	19,23%	23,53%	18,37%	16,42%	27,27%

Please indicate the extent to which you agree or disagree with each of the following statements:

# 4) The current SPC regime fosters the investment in research and development (R&D) activities

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

The current SPC regime fosters the investment in research and development	Total	General attitude towards current SPC system				
(R&D) activities		positiv	negativ			
Base	193	124	66			
Strongly agree	38,34%	55,65%	7,58%			
Agree	41,97%	34,68%	57,58%			
Disagree	12,95%	5,65%	27,27%			
Strongly disagree	2,07%	1,61%	3,03%			
Impossible to say	4,66%	2,42%	4,55%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	80,31%	90,32%	65,15%			
Disagree, Strongly disagree	15,03%	7,26%	30,30%			

Please indicate the extent to which you agree or disagree with each of the following statements:

5) The current SPC Regulations act as an incentive to increase the time span between the pre-clinical trial phase and the filing of the marketing authorisation application

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

5) The current SPC Regulations act as an incentive to increase		Total (without the later accepted				Representatives of				
the time span between the pre-clinical trial phase and the filing of the marketing	Total			Company		Law firm	Association	University/ Research	Originator	Generic
authorisation application		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	6,22%	6,15%	10,98%	15,69%	3,23%	3,17%	2,17%	-	9,09%	4,35%
Agree	20,21%	21,23%	21,95%	7,84%	45,16%	17,46%	19,57%	50,00%	11,11%	43,48%
Disagree	23,32%	22,35%	15,85%	13,73%	19,35%	44,44%	8,70%	-	18,18%	23,91%
Strongly disagree	36,27%	36,31%	37,80%	56,86%	6,45%	23,81%	52,17%	-	52,53%	10,87%
Impossible to say	13,99%	13,97%	13,41%	5,88%	25,81%	11,11%	17,39%	50,00%	9,09%	17,39%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	26,42%	27,37%	32,93%	23,53%	48,39%	20,63%	21,74%	50,00%	20,20%	47,83%
Disagree, Strongly disagree	59,59%	58,66%	53,66%	70,59%	25,81%	68,25%	60,87%	-	70,71%	34,78%

Please indicate the extent to which you agree or disagree with each of the following statements:

5) The current SPC Regulations act as an incentive to increase the time span between the pre-clinical trial phase and the filing of the marketing authorisation application

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

5) The current SPC Regulations act as an incentive to increase		Type of	law firm	Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
the time span between the pre-clinical trial phase and the filing of the marketing authorisation application	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	6,22%	-	4,88%	10,53%	14,63%	-	11,11%	15,79%	7,69%	11,76%	12,24%	8,96%	18,18%
Agree	20,21%	19,05%	17,07%	29,82%	36,59%	33,33%	33,33%	42,11%	13,46%	17,65%	26,53%	25,37%	-
Disagree	23,32%	42,86%	43,90%	17,54%	14,63%	33,33%	33,33%	15,79%	13,46%	29,41%	10,20%	14,93%	18,18%
Strongly disagree	36,27%	33,33%	19,51%	24,56%	19,51%	-	11,11%	5,26%	53,85%	35,29%	32,65%	41,79%	18,18%
Impossible to say	13,99%	4,76%	14,63%	17,54%	14,63%	33,33%	11,11%	21,05%	11,54%	5,88%	18,37%	8,96%	45,45%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	26,42%	19,05%	21,95%	40,35%	51,22%	33,33%	44,44%	57,89%	21,15%	29,41%	38,78%	34,33%	18,18%
Disagree, Strongly disagree	59,59%	76,19%	63,41%	42,11%	34,15%	33,33%	44,44%	21,05%	67,31%	64,71%	42,86%	56,72%	36,36%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

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Please indicate the extent to which you agree or disagree with each of the following statements:

5) The current SPC Regulations act as an incentive to increase the time span between the pre-clinical trial phase and the filing of the marketing authorisation application

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

5) The current SPC Regulations act as an incentive to increase the time span between the pre-clinical trial phase and the	Total	General attitude towards current SPC system				
filing of the marketing authorisation application		positiv	negativ			
Base	193	124	66			
Strongly agree	6,22%	8,06%	3,03%			
Agree	20,21%	15,32%	30,30%			
Disagree	23,32%	16,94%	34,85%			
Strongly disagree	36,27%	50,00%	12,12%			
Impossible to say	13,99%	9,68%	19,70%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	26,42%	23,39%	33,33%			
Disagree, Strongly disagree	59,59%	66,94%	46,97%			

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

6) The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the marketing authorisation is obtained

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

6) The current SPC Regulations act as an incentive to develop		Total (without the			Type of st	akeholder			Represen	tatives of
more products for which a longer time is needed until the	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
marketing authorisation is obtained		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	31,61%	31,28%	39,02%	56,86%	9,68%	14,29%	41,30%	50,00%	48,48%	10,87%
Agree	36,79%	37,43%	29,27%	13,73%	54,84%	50,79%	32,61%	-	27,27%	60,87%
Disagree	13,47%	13,97%	9,76%	15,69%	-	20,63%	10,87%	-	14,14%	-
Strongly disagree	5,18%	4,47%	3,66%	3,92%	3,23%	6,35%	6,52%	-	3,03%	2,17%
Impossible to say	12,95%	12,85%	18,29%	9,80%	32,26%	7,94%	8,70%	50,00%	7,07%	26,09%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	68,39%	68,72%	68,29%	70,59%	64,52%	65,08%	73,91%	50,00%	75,76%	71,74%
Disagree, Strongly disagree	18,65%	18,44%	13,41%	19,61%	3,23%	26,98%	17,39%	-	17,17%	2,17%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

6) The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the marketing authorisation is obtained

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

6) The current SPC Regulations act as an incentive to develop					npany, Associat esearch institution		Co	ompanies by siz	e	Position a	t company	Scope of company activities	
more products for which a longer time is needed until the marketing authorisation is obtained	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	31,61%	28,57%	7,32%	33,33%	34,15%	-	11,11%	10,53%	55,77%	58,82%	28,57%	43,28%	18,18%
Agree	36,79%	42,86%	56,10%	29,82%	29,27%	66,67%	66,67%	26,32%	23,08%	17,65%	32,65%	29,85%	18,18%
Disagree	13,47%	14,29%	21,95%	8,77%	9,76%	-	11,11%	10,53%	7,69%	11,76%	10,20%	8,96%	9,09%
Strongly disagree	5,18%	14,29%	2,44%	5,26%	4,88%	-	11,11%	5,26%	1,92%	5,88%	2,04%	4,48%	-
Impossible to say	12,95%	-	12,20%	22,81%	21,95%	33,33%	-	47,37%	11,54%	5,88%	26,53%	13,43%	54,55%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	68,39%	71,43%	63,41%	63,16%	63,41%	66,67%	77,78%	36,84%	78,85%	76,47%	61,22%	73,13%	36,36%
Disagree, Strongly disagree	18,65%	28,57%	24,39%	14,04%	14,63%	-	22,22%	15,79%	9,62%	17,65%	12,24%	13,43%	9,09%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

6) The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the marketing authorisation is obtained

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

6) The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the	Total	General attitude towards current SPC system				
marketing authorisation is obtained		positiv	negativ			
Base	193	124	66			
Strongly agree	31,61%	44,35%	9,09%			
Agree	36,79%	30,65%	50,00%			
Disagree	13,47%	14,52%	12,12%			
Strongly disagree	5,18%	6,45%	3,03%			
Impossible to say	12,95%	4,03%	25,76%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	68,39%	75,00%	59,09%			
Disagree, Strongly disagree	18,65%	20,97% 15,15%				

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

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Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 7) The current SPC Regulations work well in most cases and do not result in legal uncertainty

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Represer	tatives of
7) The current SPC Regulations work well in most cases and do not result in legal uncertainty	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
,		partici- pants)	Total	Originator	Generic		7.0000.00.00.00.00.00.00.00.00.00.00.00.	institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	27,46%	27,93%	37,80%	56,86%	6,45%	7,94%	36,96%	<u>-</u>	45,45%	6,52%
Agree	25,91%	26,82%	20,73%	25,49%	12,90%	31,75%	28,26%	-	28,28%	13,04%
Disagree	23,32%	24,02%	19,51%	7,84%	38,71%	38,10%	8,70%	50,00%	16,16%	30,43%
Strongly disagree	20,21%	17,88%	19,51%	5,88%	41,94%	19,05%	23,91%	-	7,07%	47,83%
Impossible to say	3,11%	3,35%	2,44%	3,92%	-	3,17%	2,17%	50,00%	3,03%	2,17%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	53,37%	54,75%	58,54%	82,35%	19,35%	39,68%	65,22%	-	73,74%	19,57%
Disagree, Strongly disagree	43,52%	41,90%	39,02%	13,73%	80,65%	57,14%	32,61%	50,00%	23,23%	78,26%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 7) The current SPC Regulations work well in most cases and do not result in legal uncertainty

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of	law firm	Company, Association, University/research institution is located			C	ompanies by siz	е	Position a	t company	Scope of company activities	
The current SPC Regulations work well in most cases and do not result in legal uncertainty	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	27,46%	19,05%	2,44%	26,32%	21,95%	-	11,11%	15,79%	50,00%	41,18%	32,65%	40,30%	27,27%
Agree	25,91%	33,33%	31,71%	24,56%	29,27%	-	66,67%	21,05%	13,46%	23,53%	18,37%	20,90%	9,09%
Disagree	23,32%	28,57%	41,46%	21,05%	24,39%	33,33%	-	26,32%	21,15%	17,65%	24,49%	20,90%	18,18%
Strongly disagree	20,21%	19,05%	19,51%	24,56%	19,51%	66,67%	22,22%	26,32%	15,38%	17,65%	20,41%	16,42%	36,36%
Impossible to say	3,11%	-	4,88%	3,51%	4,88%	-	-	10,53%	-	-	4,08%	1,49%	9,09%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	53,37%	52,38%	34,15%	50,88%	51,22%	-	77,78%	36,84%	63,46%	64,71%	51,02%	61,19%	36,36%
Disagree, Strongly disagree	43,52%	47,62%	60,98%	45,61%	43,90%	100,00%	22,22%	52,63%	36,54%	35,29%	44,90%	37,31%	54,55%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 7) The current SPC Regulations work well in most cases and do not result in legal uncertainty

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

7) The current SPC Regulations work well in most cases and do	Total	General attitude towards current SPC system				
not result in legal uncertainty		positiv	negativ			
Base	193	124	66			
Strongly agree	27,46%	42,74%	-			
Agree	25,91%	40,32%	-			
Disagree	23,32%	12,10%	45,45%			
Strongly disagree	20,21%	3,23%	53,03%			
Impossible to say	3,11%	1,61%	1,52%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	53,37%	83,06%	-			
Disagree, Strongly disagree	43,52%	15,32%	98,48%			

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 8) The SPC Regulations, as interpreted by the CJEU, encourage investment in the development of combination products in Europe

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

8) The SPC Regulations, as		Total (without the			Type of st	akeholder			Represer	ntatives of
interpreted by the CJEU, encourage investment in the development of combination	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
products in Europe		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	7,25%	7,26%	10,98%	13,73%	6,45%	3,17%	6,52%	<u>-</u>	11,11%	4,35%
Agree	37,82%	40,22%	37,80%	31,37%	48,39%	26,98%	52,17%	50,00%	32,32%	52,17%
Disagree	24,87%	25,14%	20,73%	19,61%	22,58%	42,86%	8,70%	-	23,23%	19,57%
Strongly disagree	5,70%	4,47%	3,66%	1,96%	6,45%	9,52%	4,35%	-	5,05%	6,52%
Impossible to say	24,35%	22,91%	26,83%	33,33%	16,13%	17,46%	28,26%	50,00%	28,28%	17,39%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	45,08%	47,49%	48,78%	45,10%	54,84%	30,16%	58,70%	50,00%	43,43%	56,52%
Disagree, Strongly disagree	30,57%	29,61%	24,39%	21,57%	29,03%	52,38%	13,04%	-	28,28%	26,09%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 8) The SPC Regulations, as interpreted by the CJEU, encourage investment in the development of combination products in Europe

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

8) The SPC Regulations, as		Type of	law firm	Company, Association, University/research institution is located			C	ompanies by siz	е	Position a	t company	Scope of company activities	
interpreted by the CJEU, encourage investment in the development of combination products in Europe	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	7,25%	9,52%	-	5,26%	7,32%	-	11,11%	5,26%	13,46%	17,65%	10,20%	10,45%	18,18%
Agree	37,82%	19,05%	31,71%	36,84%	31,71%	33,33%	33,33%	31,58%	42,31%	35,29%	34,69%	41,79%	18,18%
Disagree	24,87%	23,81%	51,22%	24,56%	24,39%	33,33%	33,33%	26,32%	15,38%	23,53%	26,53%	19,40%	18,18%
Strongly disagree	5,70%	14,29%	7,32%	3,51%	2,44%	16,67%	-	5,26%	3,85%	-	4,08%	2,99%	9,09%
Impossible to say	24,35%	33,33%	9,76%	29,82%	34,15%	16,67%	22,22%	31,58%	25,00%	23,53%	24,49%	25,37%	36,36%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	45,08%	28,57%	31,71%	42,11%	39,02%	33,33%	44,44%	36,84%	55,77%	52,94%	44,90%	52,24%	36,36%
Disagree, Strongly disagree	30,57%	38,10%	58,54%	28,07%	26,83%	50,00%	33,33%	31,58%	19,23%	23,53%	30,61%	22,39%	27,27%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

8) The SPC Regulations, as interpreted by the CJEU, encourage investment in the development of combination products in Europe

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

8) The SPC Regulations, as interpreted by the CJEU, encourage investment in the	Total	General attitude towards current SPC system				
development of combination products in Europe		positiv	negativ			
Base	193	124	66			
Strongly agree	7,25%	9,68%	3,03%			
Agree	37,82%	40,32%	34,85%			
Disagree	24,87%	18,55%	37,88%			
Strongly disagree	5,70%	4,03%	9,09%			
Impossible to say	24,35%	27,42%	15,15%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	45,08%	50,00%	37,88%			
Disagree, Strongly disagree	30,57%	22,58%	46,97%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

9) The SPC Regulations, as interpreted by the CJEU, sufficiently protect new medical uses of known compounds (second medical use)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

9) The SPC Regulations, as		Total (without the			Type of st	akeholder			Representatives o	
interpreted by the CJEU, sufficiently protect new medical uses of known compounds	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
(second medical use)		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	6,22%	6,15%	12,20%	13,73%	9,68%	-	2,17%	50,00%	7,07%	6,52%
Agree	56,48%	56,42%	58,54%	56,86%	61,29%	50,79%	63,04%	-	60,61%	65,22%
Disagree	16,58%	16,76%	14,63%	13,73%	16,13%	25,40%	8,70%	-	15,15%	17,39%
Strongly disagree	6,74%	6,70%	2,44%	-	6,45%	14,29%	4,35%	-	4,04%	4,35%
Impossible to say	13,99%	13,97%	12,20%	15,69%	6,45%	9,52%	21,74%	50,00%	13,13%	6,52%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	62,69%	62,57%	70,73%	70,59%	70,97%	50,79%	65,22%	50,00%	67,68%	71,74%
Disagree, Strongly disagree	23,32%	23,46%	17,07%	13,73%	22,58%	39,68%	13,04%	-	19,19%	21,74%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 9) The SPC Regulations, as interpreted by the CJEU, sufficiently protect new medical uses of known compounds (second medical use)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

9) The SPC Regulations, as	Type of law firm  Type of law firm				npany, Associa esearch institution		C	ompanies by siz	e	Position a	t company	Scope of company activities	
interpreted by the CJEU, sufficiently protect new medical uses of known compounds (second medical use)	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	6,22%	-	-	10,53%	12,20%	-	11,11%	-	15,38%	17,65%	8,16%	11,94%	9,09%
Agree	56,48%	38,10%	56,10%	54,39%	48,78%	50,00%	55,56%	47,37%	63,46%	47,06%	61,22%	62,69%	45,45%
Disagree	16,58%	38,10%	19,51%	14,04%	12,20%	33,33%	11,11%	21,05%	13,46%	23,53%	14,29%	13,43%	18,18%
Strongly disagree	6,74%	19,05%	12,20%	3,51%	4,88%	-	-	10,53%	-	-	4,08%	2,99%	-
Impossible to say	13,99%	4,76%	12,20%	17,54%	21,95%	16,67%	22,22%	21,05%	7,69%	11,76%	12,24%	8,96%	27,27%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	62,69%	38,10%	56,10%	64,91%	60,98%	50,00%	66,67%	47,37%	78,85%	64,71%	69,39%	74,63%	54,55%
Disagree, Strongly disagree	23,32%	57,14%	31,71%	17,54%	17,07%	33,33%	11,11%	31,58%	13,46%	23,53%	18,37%	16,42%	18,18%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

9) The SPC Regulations, as interpreted by the CJEU, sufficiently protect new medical uses of known compounds (second medical use)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

9) The SPC Regulations, as interpreted by the CJEU, sufficiently protect new medical	Total	General attitude towards current SPC system				
uses of known compounds (second medical use)		positiv	negativ			
Base	193	124	66			
Strongly agree	6,22%	5,65%	7,58%			
Agree	56,48%	61,29%	50,00%			
Disagree	16,58%	14,52%	21,21%			
Strongly disagree	6,74%	4,03%	12,12%			
Impossible to say	13,99%	14,52%	9,09%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	62,69%	66,94%	57,58%			
Disagree, Strongly disagree	23,32%	18,55% 33,33%				

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 10) When it comes to examining SPC applications, the practice and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

10) When it comes to examining SPC applications, the practice		Total			Type of st	akeholder			Represer	ntatives of
and procedures of the national offices in the EU Member States differ significantly in terms of	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
predictability, transparency and quality of the rights granted		pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	28,50%	29,05%	31,71%	21,57%	48,39%	26,98%	23,91%	50,00%	18,18%	43,48%
Agree	33,16%	32,96%	24,39%	19,61%	32,26%	46,03%	32,61%	-	29,29%	39,13%
Disagree	23,83%	23,46%	29,27%	47,06%	-	20,63%	19,57%	-	39,39%	-
Strongly disagree	2,59%	2,79%	2,44%	1,96%	3,23%	1,59%	4,35%	-	2,02%	4,35%
Impossible to say	11,92%	11,73%	12,20%	9,80%	16,13%	4,76%	19,57%	50,00%	11,11%	13,04%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	61,66%	62,01%	56,10%	41,18%	80,65%	73,02%	56,52%	50,00%	47,47%	82,61%
Disagree, Strongly disagree	26,42%	26,26%	31,71%	49,02%	3,23%	22,22%	23,91%		41,41%	4,35%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

# 10) When it comes to examining SPC applications, the practice and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

10) When it comes to examining SPC applications, the practice		Type of law firm			npany, Associat esearch institution		C	ompanies by siz	е	Position a	t company	Scope of company activities	
and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	28,50%	23,81%	26,83%	38,60%	39,02%	50,00%	33,33%	52,63%	25,00%	5,88%	38,78%	32,84%	36,36%
Agree	33,16%	33,33%	53,66%	22,81%	24,39%	50,00%	33,33%	15,79%	23,08%	35,29%	22,45%	22,39%	18,18%
Disagree	23,83%	38,10%	12,20%	19,30%	14,63%	-	11,11%	5,26%	42,31%	35,29%	26,53%	32,84%	18,18%
Strongly disagree	2,59%	-	2,44%	3,51%	4,88%	-	-	5,26%	1,92%	-	4,08%	2,99%	-
Impossible to say	11,92%	4,76%	4,88%	15,79%	17,07%	-	22,22%	21,05%	7,69%	23,53%	8,16%	8,96%	27,27%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	61,66%	57,14%	80,49%	61,40%	63,41%	100,00%	66,67%	68,42%	48,08%	41,18%	61,22%	55,22%	54,55%
Disagree, Strongly disagree	26,42%	38,10%	14,63%	22,81%	19,51%	-	11,11%	10,53%	44,23%	35,29%	30,61%	35,82%	18,18%

Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

10) When it comes to examining SPC applications, the practice and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

10) When it comes to examining SPC applications, the practice and procedures of the national offices in the EU Member States differ significantly in terms of	Total	General attitude towards current SPC system				
predictability, transparency and quality of the rights granted		positiv	negativ			
Base	193	124	66			
Strongly agree	28,50%	19,35%	46,97%			
Agree	33,16%	30,65%	37,88%			
Disagree	23,83%	35,48%	3,03%			
Strongly disagree	2,59%	4,03%	-			
Impossible to say	11,92%	10,48%	12,12%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	61,66%	50,00%	84,85%			
Disagree, Strongly disagree	26,42%	39,52%	3,03%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 27

Regulation 1768/92/EEC (now Regulation 469/2009/EC) was conceived with traditional chemical compounds in mind.

In the meantime, biopharmaceuticals and products of recombinant DNA technology (such as proteins, antibodies, microbes, cells and cell lines, vaccines, viruses, DNA/RNA sequences or products for gene therapy) have grown in importance.

In your opinion, does the present system adequately accommodate this technical development?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Represer	ntatives of	
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Yes	45,60%	46,93%	50,00%	62,75%	29,03%	25,40%	65,22%	50,00%	55,56%	39,13%	
No	32,12%	32,40%	21,95%	17,65%	29,03%	60,32%	13,04%	-	25,25%	30,43%	
No opinion	22,28%	20,67%	28,05%	19,61%	41,94%	14,29%	21,74%	50,00%	19,19%	30,43%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

		Type of	Type of law firm		npany, Associat search institutio	ion, on is located	Co	ompanies by siz	ze	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Yes	45,60%	28,57%	24,39%	42,11%	34,15%	33,33%	44,44%	10,53%	63,46%	52,94%	42,86%	53,73%	27,27%
No	32,12%	57,14%	60,98%	24,56%	26,83%	50,00%	22,22%	36,84%	17,31%	17,65%	28,57%	20,90%	27,27%
No opinion	22,28%	14,29%	14,63%	33,33%	39,02%	16,67%	33,33%	52,63%	19,23%	29,41%	28,57%	25,37%	45,45%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 27

Regulation 1768/92/EEC (now Regulation 469/2009/EC) was conceived with traditional chemical compounds in mind.

In the meantime, biopharmaceuticals and products of recombinant DNA technology (such as proteins, antibodies, microbes, cells and cell lines, vaccines, viruses, DNA/RNA sequences or products for gene therapy) have grown in importance.

In your opinion, does the present system adequately accommodate this technical development?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attit current SF	ude towards C system
		positiv	negativ
Base	193	124	66
Yes	45,60%	55,65%	28,79%
No	32,12%	26,61%	42,42%
No opinion	22,28%	17,74%	28,79%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Question 28
Please explain why you think the present system does not adequately accommodate biopharmaceuticals and products of recombinant DNA technology.

Base = all respondents who answered "no" in Q27

		Total (without the later accepted partici-			Type of st	akeholder			Represer	ntatives of	
	Total			Company		Law firm	Association	University/ Research	Originator	Generic	
		pants)	Total	Originator	Generic			institution	companies	companies	
Base	62	58	18	9	9	38	6	-	25	14	
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	83,87%	86,21%	83,33%	88,89%	77.78%	84.21%	83.33%		80.00%	78,57%	
section verbaums)	83,87%	80,21%	83,33%	88,89%	11,18%	84,21%	83,33%	-	80,00%	18,51%	
I have no opinion on that	16,13%	13,79%	16,67%	11,11%	22,22%	15,79%	16,67%	-	20,00%	21,43%	

				Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	62	12	25	14	11	3	2	7	9	3	14	14	3
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	83,87%	91,67%	84,00%	85,71%	81,82%	100,00%	100,00%	85,71%	77,78%	100,00%	85,71%	78,57%	100,00%
I have no opinion on that	16,13%	8,33%	16,00%	14,29%	18,18%	-	1	14,29%	22,22%	-	14,29%	21,43%	•

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	62	33	28			
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	83,87%	87,88%	78,57%			
I have no opinion on that	16,13%	12,12% 21,43%				

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# Ouestion 29

In your opinion, does Regulation 469/2009/EC need to be changed or amended in order to better accommodate biopharmaceuticals and products of recombinant DNA technology?

Base = all respondents who answered "no" in Q27

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted		Company		. Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	62	58	18	9	9	38	6	-	25	14	
Yes	72,58%	74,14%	61,11%	77,78%	44,44%	73,68%	100,00%	<u>-</u>	76,00%	57,14%	
No	12,90%	12,07%	5,56%	-	11,11%	18,42%	-	-	8,00%	14,29%	
No opinion	14,52%	13,79%	33,33%	22,22%	44,44%	7,89%	-	-	16,00%	28,57%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	100,00%	100,00%	

		Type of	Type of law firm		npany, Associat search institution	ion, on is located	С	ompanies by siz	e	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	62	12	25	14	11	3	2	7	9	3	14	14	3
Yes	72,58%	75,00%	72,00%	64,29%	72,73%	33,33%	100,00%	85,71%	33,33%	66,67%	64,29%	57,14%	66,67%
No	12,90%	16,67%	20,00%	7,14%	9,09%	-	-	14,29%	-	-	7,14%	7,14%	-
No opinion	14,52%	8,33%	8,00%	28,57%	18,18%	66,67%	-	-	66,67%	33,33%	28,57%	35,71%	33,33%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Ouestion 29

In your opinion, does Regulation 469/2009/EC need to be changed or amended in order to better accommodate biopharmaceuticals and products of recombinant DNA technology?

Base = all respondents who answered "no" in Q27

	Total	General attit current SF	
		positiv	negativ
Base	62	33	28
Yes	72,58%	78,79%	64,29%
No	12,90%	18,18%	7,14%
No opinion	14,52%	3,03%	28,57%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Ouestion 30

In your opinion, what specific changes or amendments are needed with respect to Regulation 469/2009/EC and/or Regulation 1610/96/EC in order to better accommodate these technical developments?

Base = all respondents who answered "no" in Q27 and "yes" in Q29

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		pants)	Total Originator Generic				institution	companies	companies		
Base	45	43	11	7	4	28	6	-	19	8	
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	71,11%	72,09%	81,82%	100,00%	50,00%	71,43%	50,00%	-	73,68%	50,00%	
I have no opinion on that	28,89%	27,91%	18,18%	-	50,00%	28,57%	50,00%	-	26,32%	50,00%	

		Type of	of law firm  Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	45	9	18	9	8	1	2	6	3	2	9	8	2
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")  I have no opinion on that	71,11% 28,89%	88,89% 11,11%	66,67% 33,33%	77,78% 22,22%	75,00% 25,00%	100,00% -	50,00% 50,00%	83,33% 16,67%	100,00% -	100,00% -	77,78% 22,22%	75,00% 25,00%	100,00% -

	Total	General attit current SF	
		positiv	negativ
Base	45	26	18
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	71,11%	69,23%	72,22%
I have no opinion on that	28,89%	30,77%	27,78%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# Question 31 Do you think that the current SPC Regulations have encouraged "evergreening" strategies?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Representatives of		
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Yes, to a great extent	12,44%	11,17%	17,07%	1,96%	41,94%	4,76%	15,22%	-	1,01%	43,48%	
Yes, somewhat	19,69%	20,67%	17,07%	5,88%	35,48%	30,16%	8,70%	50,00%	12,12%	32,61%	
No, not substantially	61,14%	60,89%	58,54%	82,35%	19,35%	61,90%	67,39%	-	78,79%	21,74%	
Impossible to say, no opinion	6,74%	7,26%	7,32%	9,80%	3,23%	3,17%	8,70%	50,00%	8,08%	2,17%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

		Type of	law firm	Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Yes, to a great extent	12,44%	4,76%	4,88%	22,81%	21,95%	50,00%	11,11%	21,05%	17,31%	11,76%	18,37%	17,91%	18,18%
Yes, somewhat	19,69%	9,52%	39,02%	21,05%	19,51%	33,33%	44,44%	26,32%	7,69%	29,41%	14,29%	16,42%	18,18%
No, not substantially	61,14%	76,19%	56,10%	45,61%	48,78%	16,67%	33,33%	31,58%	73,08%	52,94%	59,18%	61,19%	45,45%
Impossible to say, no opinion	6,74%	9,52%	-	10,53%	9,76%	-	11,11%	21,05%	1,92%	5,88%	8,16%	4,48%	18,18%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Question 31 Do you think that the current SPC Regulations have encouraged "evergreening" strategies?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
Yes, to a great extent	12,44%	3,23%	30,30%			
Yes, somewhat	19,69%	15,32%	28,79%			
No, not substantially	61,14%	74,19%	37,88%			
Impossible to say, no opinion	6,74%	7,26%	3,03%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

# Question 32

In your view, what specific aspects of the SPC Regulations have encouraged "evergreening" strategies? Please explain.

Base = all respondents who answered "yes" in Q31

		Total (without the			Type of st	akeholder			Representatives of		
	Total	\` lator		Company		Law firm	Association	University/ Research	Originator	Generic	
	partici- pants)		Total	Originator	Generic			institution	companies	companies	
Base	62	57	28	4	24	22	11	1	13	35	
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	72,58%	70,18%	82,14%	100,00%	79,17%	50,00%	90,91%	100,00%	38,46%	85,71%	
I have no opinion on that	27,42%	29,82%	17,86%	-	20,83%	50,00%	9,09%	-	61,54%	14,29%	

		Type of law firm			Company, Association, University/research institution is located			ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	62	3	18	25	17	5	5	9	13	7	16	23	4
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	72,58%	33,33%	50,00%	80,00%	70,59%	100,00%	100,00%	66,67%	84,62%	71,43%	81,25%	78,26%	100,00%
I have no opinion on that	27,42%	66,67%	50,00%	20,00%	29,41%	-	-	33,33%	15,38%	28,57%	18,75%	21,74%	1

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	62	23	39			
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	72,58%	52,17%	84,62%			
I have no opinion on that	27,42%	47,83%	15,38%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 33

In your opinion, which of the following development activities should be covered by SPCs? (Multiple responses possible)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Represer	ntatives of
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total Originator Generic			institution	companies	companies		
Base	193	179	82	51	31	63	46	2	99	46
The development of new active ingredients	91,71%	92,74%	95,12%	94,12%	96,77%	93,65%	84,78%	50,00%	95,96%	93,48%
The development of new formulations of existing active ingredients	59,59%	60,34%	56,10%	80,39%	16,13%	63,49%	63,04%	-	79,80%	23,91%
The development of new indications for existing active ingredients	74,09%	74,86%	63,41%	86,27%	25,81%	87,30%	76,09%	50,00%	89,90%	36,96%
The development of new derivatives of existing active ingredients	62,18%	62,01%	57,32%	82,35%	16,13%	66,67%	67,39%	-	80,81%	23,91%
Sum of answers	287,56%	289,94%	271,95%	343,14%	154,84%	311,11%	291,30%	100,00%	346,46%	178,26%
No response	4,66%	3,35%	3,66%	5,88%	-	-	10,87%	50,00%	3,03%	2,17%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 33

In your opinion, which of the following development activities should be covered by SPCs? (Multiple responses possible)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of	law firm	Company, Association, University/research institution is located			Co	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
The development of new active ingredients	91,71%	90,48%	95,12%	92,98%	92,68%	100,00%	88,89%	89,47%	98,08%	88,24%	95,92%	95,52%	90,91%
The development of new formulations of existing active ingredients	59,59%	71,43%	58,54%	42,11%	41,46%	-	22,22%	42,11%	67,31%	52,94%	55,10%	59,70%	36,36%
The development of new indications for existing active ingredients	74,09%	80,95%	90,24%	50,88%	48,78%	16,67%	66,67%	26,32%	76,92%	52,94%	61,22%	64,18%	54,55%
The development of new derivatives of existing active ingredients	62,18%	71,43%	65,85%	43,86%	46,34%	-	22,22%	36,84%	71,15%	52,94%	57,14%	58,21%	54,55%
Sum of answers	287,56%	314,29%	309,76%	229,82%	229,27%	116,67%	200,00%	194,74%	313,46%	247,06%	269,39%	277,61%	236,36%
No response	4,66%	-	-	5,26%	4,88%	-	11,11%	5,26%	1,92%	11,76%	2,04%	2,99%	9,09%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 33

In your opinion, which of the following development activities should be covered by SPCs? (Multiple responses possible)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
The development of new active ingredients	91,71%	93,55%	89,39%			
The development of new formulations of existing active ingredients	59,59%	75,00%	33,33%			
The development of new indications for existing active ingredients	74,09%	83,87%	56,06%			
The development of new derivatives of existing active ingredients	62,18%	75,81%	39,39%			
Sum of answers	287,56%	328,23%	218,18%			
No response	4,66%	4,03%	4,55%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

#### **Ouestion 34**

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

# 1) ... compared to the development of new forms of existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Representatives of	
compared to the development of new forms of existing active ingredients.	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	20,73%	20,67%	28,05%	19,61%	41,94%	20,63%	6,52%	50,00%	16,16%	39,13%
Agree	31,61%	31,28%	24,39%	9,80%	48,39%	36,51%	36,96%	50,00%	18,18%	43,48%
Disagree	16,58%	17,32%	7,32%	9,80%	3,23%	30,16%	15,22%	-	17,17%	8,70%
Strongly disagree	18,13%	18,44%	28,05%	43,14%	3,23%	-	26,09%	-	31,31%	4,35%
Impossible to say	11,92%	12,29%	12,20%	17,65%	3,23%	12,70%	10,87%	-	17,17%	2,17%
No response	1,04%	-	-	-	-	-	4,35%	-	-	2,17%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	52,33%	51,96%	52,44%	29,41%	90,32%	57,14%	43,48%	100,00%	34,34%	82,61%
Disagree, Strongly disagree	34,72%	35,75%	35,37%	52,94%	6,45%	30,16%	41,30%	-	48,48%	13,04%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

1) ... compared to the development of new forms of existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

compared to the development of new forms of existing active ingredients.		Type of	law firm	Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	20,73%	23,81%	17,07%	33,33%	34,15%	33,33%	55,56%	21,05%	25,00%	35,29%	24,49%	23,88%	45,45%
Agree	31,61%	33,33%	39,02%	29,82%	31,71%	50,00%	33,33%	47,37%	15,38%	11,76%	32,65%	25,37%	27,27%
Disagree	16,58%	33,33%	29,27%	10,53%	12,20%	16,67%	11,11%	5,26%	7,69%	-	8,16%	7,46%	-
Strongly disagree	18,13%	-	-	17,54%	14,63%	-	-	-	42,31%	35,29%	24,49%	31,34%	9,09%
Impossible to say	11,92%	9,52%	14,63%	8,77%	7,32%	-	-	26,32%	9,62%	17,65%	10,20%	11,94%	18,18%
No response	1,04%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	52,33%	57,14%	56,10%	63,16%	65,85%	83,33%	88,89%	68,42%	40,38%	47,06%	57,14%	49,25%	72,73%
Disagree, Strongly disagree	34,72%	33,33%	29,27%	28,07%	26,83%	16,67%	11,11%	5,26%	50,00%	35,29%	32,65%	38,81%	9,09%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

1) ... compared to the development of new forms of existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

compared to the development of new forms of	Total	General attitude towards current SPC system				
existing active ingredients.		positiv	negativ			
Base	193	124	66			
Strongly agree	20,73%	13,71%	34,85%			
Agree	31,61%	20,97%	50,00%			
Disagree	16,58%	20,97%	9,09%			
Strongly disagree	18,13%	28,23%	-			
Impossible to say	11,92%	16,13%	3,03%			
No response	1,04%	-	3,03%			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	52,33%	34,68%	84,85%			
Disagree, Strongly disagree	34,72%	49,19%	9,09%			

# Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

# 2) ...compared to the development of new formulations of existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

2)compared to the		Total (without the later accepted			Type of st	akeholder			Representatives of	
development of new formulations of existing active ingredients.	Total			Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total Originator Gen		Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	20,21%	20,11%	26,83%	17,65%	41,94%	20,63%	6,52%	50,00%	15,15%	36,96%
Agree	30,05%	31,28%	20,73%	3,92%	48,39%	36,51%	36,96%	50,00%	14,14%	47,83%
Disagree	20,73%	20,67%	14,63%	19,61%	6,45%	33,33%	15,22%	-	24,24%	8,70%
Strongly disagree	18,13%	17,88%	26,83%	41,18%	3,23%	1,59%	26,09%	-	31,31%	4,35%
Impossible to say	9,84%	10,06%	10,98%	17,65%	-	7,94%	10,87%	-	15,15%	-
No response	1,04%	-	-	-	-	-	4,35%	-	-	2,17%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	50,26%	51,40%	47,56%	21,57%	90,32%	57,14%	43,48%	100,00%	29,29%	84,78%
Disagree, Strongly disagree	38,86%	38,55%	41,46%	60,78%	9,68%	34,92%	41,30%	-	55,56%	13,04%

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

# 2) ...compared to the development of new formulations of existing active ingredients.

Base all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

2)compared to the development of new formulations of existing active ingredients.		Type of law firm		Company, Association, University/research institution is located			Co	ompanies by siz	е	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	20,21%	28,57%	14,63%	33,33%	36,59%	33,33%	55,56%	26,32%	21,15%	17,65%	28,57%	22,39%	45,45%
Agree	30,05%	19,05%	46,34%	26,32%	26,83%	50,00%	22,22%	42,11%	13,46%	17,65%	24,49%	22,39%	18,18%
Disagree	20,73%	38,10%	31,71%	15,79%	17,07%	16,67%	22,22%	15,79%	13,46%	11,76%	16,33%	14,93%	9,09%
Strongly disagree	18,13%	4,76%	-	17,54%	14,63%	-	-	-	40,38%	29,41%	24,49%	29,85%	9,09%
Impossible to say	9,84%	9,52%	7,32%	7,02%	4,88%	-	-	15,79%	11,54%	23,53%	6,12%	10,45%	18,18%
No response	1,04%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	50,26%	47,62%	60,98%	59,65%	63,41%	83,33%	77,78%	68,42%	34,62%	35,29%	53,06%	44,78%	63,64%
Disagree, Strongly disagree	38,86%	42,86%	31,71%	33,33%	31,71%	16,67%	22,22%	15,79%	53,85%	41,18%	40,82%	44,78%	18,18%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

# 2) ...compared to the development of new formulations of existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

2)compared to the development of new formulations of existing active	Total	General attitude towards current SPC system				
ingredients.		positiv	negativ			
Base	193	124	66			
Strongly agree	20,21%	12,90%	34,85%			
Agree	30,05%	21,77%	43,94%			
Disagree	20,73%	25,00%	13,64%			
Strongly disagree	18,13%	27,42%	1,52%			
Impossible to say	9,84%	12,90%	3,03%			
No response	1,04%	-	3,03%			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	50,26%	34,68%	78,79%			
Disagree, Strongly disagree	38,86%	52,42%	15,15%			

# Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

# 3) ...compared to the development of new indications for existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the later accepted			Type of st	akeholder			Representatives of	
3)compared to the development of new indications for existing active ingredients.	Total			Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Strongly agree	7,77%	7,26%	12,20%	11,76%	12,90%	4,76%	4,35%	-	9,09%	13,04%
Agree	31,09%	31,84%	30,49%	11,76%	61,29%	30,16%	30,43%	100,00%	16,16%	54,35%
Disagree	27,46%	27,37%	15,85%	13,73%	19,35%	49,21%	19,57%	-	24,24%	23,91%
Strongly disagree	19,17%	19,55%	29,27%	47,06%	-	1,59%	26,09%	-	33,33%	2,17%
Impossible to say	13,47%	13,97%	12,20%	15,69%	6,45%	14,29%	15,22%	-	17,17%	4,35%
No response	1,04%	-	-	-	-	-	4,35%	-	-	2,17%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	38,86%	39,11%	42,68%	23,53%	74,19%	34,92%	34,78%	100,00%	25,25%	67,39%
Disagree, Strongly disagree	46,63%	46,93%	45,12%	60,78%	19,35%	50,79%	45,65%	-	57,58%	26,09%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

# 3) ...compared to the development of new indications for existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
3)compared to the development of new indications for existing active ingredients.	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Strongly agree	7,77%	9,52%	2,44%	14,04%	17,07%	-	22,22%	10,53%	9,62%	5,88%	14,29%	10,45%	18,18%
Agree	31,09%	28,57%	29,27%	36,84%	41,46%	33,33%	55,56%	47,37%	21,15%	35,29%	30,61%	29,85%	27,27%
Disagree	27,46%	47,62%	51,22%	19,30%	19,51%	33,33%	22,22%	21,05%	13,46%	11,76%	16,33%	14,93%	27,27%
Strongly disagree	19,17%	4,76%	-	19,30%	17,07%	-	-	5,26%	42,31%	29,41%	28,57%	32,84%	9,09%
Impossible to say	13,47%	9,52%	17,07%	10,53%	4,88%	33,33%	-	15,79%	13,46%	17,65%	10,20%	11,94%	18,18%
No response	1,04%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	38,86%	38,10%	31,71%	50,88%	58,54%	33,33%	77,78%	57,89%	30,77%	41,18%	44,90%	40,30%	45,45%
Disagree, Strongly disagree	46,63%	52,38%	51,22%	38,60%	36,59%	33,33%	22,22%	26,32%	55,77%	41,18%	44,90%	47,76%	36,36%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 34

Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection...

3) ...compared to the development of new indications for existing active ingredients.

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

3)compared to the development of new indications	Total	General attitude towards current SPC system				
for existing active ingredients.		positiv	negativ			
Base	193	124	66			
Strongly agree	7,77%	5,65%	12,12%			
Agree	31,09%	22,58%	46,97%			
Disagree	27,46%	26,61%	30,30%			
Strongly disagree	19,17%	29,84%	-			
Impossible to say	13,47%	15,32%	7,58%			
No response	1,04%	-	3,03%			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	38,86%	28,23%	59,09%			
Disagree, Strongly disagree	46,63%	56,45%	30,30%			

# Question 35

It is sometimes said that there is insufficient investment in the development of new antibiotics. Would you favour or oppose changing Regulation 469/2009/EC in response to this assumed deficit?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Represer	ntatives of
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Favour	23,32%	22,91%	20,73%	17,65%	25,81%	36,51%	8,70%	50,00%	23,23%	19,57%
Oppose	48,70%	49,16%	52,44%	60,78%	38,71%	33,33%	65,22%	-	55,56%	45,65%
Impossible to say, no opinion	27,98%	27,93%	26,83%	21,57%	35,48%	30,16%	26,09%	50,00%	21,21%	34,78%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of law firm		Con University/re	npany, Associat search institution	ion, on is located	С	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Favour	23,32%	28,57%	41,46%	24,56%	26,83%	16,67%	33,33%	36,84%	11,54%	23,53%	24,49%	17,91%	27,27%
Oppose	48,70%	47,62%	24,39%	45,61%	43,90%	33,33%	44,44%	10,53%	69,23%	41,18%	44,90%	58,21%	27,27%
Impossible to say, no opinion	27,98%	23,81%	34,15%	29,82%	29,27%	50,00%	22,22%	52,63%	19,23%	35,29%	30,61%	23,88%	45,45%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 35

It is sometimes said that there is insufficient investment in the development of new antibiotics. Would you favour or oppose changing Regulation 469/2009/EC in response to this assumed deficit?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
Favour	23,32%	20,16%	28,79%			
Oppose	48,70%	57,26%	34,85%			
Impossible to say, no opinion	27,98%	22,58%	36,36%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Question 36
What changes would you propose in response to insufficient investment in the development of new antibiotics?

Base = all respondents who answered "Favour" in Q35

		Total (without the			Type of st	akeholder			Represer	sentatives of	
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		pants)	Total	Originator	Generic			institution	companies	companies	
Base	45	41	17	9	8	23	4	1	23	9	
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	55,56%	56,10%	64,71%	44,44%	87,50%	43,48%	75,00%	100,00%	39,13%	77,78%	
Don't know	44,44%	43,90%	35,29%	55,56%	12,50%	56,52%	25,00%	-	60,87%	22,22%	

		Type of law firm		Con University/re	npany, Associat esearch institution	tion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	45	6	17	14	11	1	3	7	6	4	12	12	3
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	55,56%	33,33%	47,06%	71,43%	72,73%	100,00%	66,67%	57,14%	66,67%	100,00%	50,00%	58,33%	100,00%
Don't know	44,44%	66,67%	52,94%	28,57%	27,27%	-	33,33%	42,86%	33,33%	-	50,00%	41,67%	-

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	45	25	19			
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	55,56%	52,00%	63,16%			
Don't know	44,44%	48,00%	36,84%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# Ouestion 37

It is sometimes said that there is insufficient investment in the development of some categories of orphan drugs. Would you favour or oppose changing Regulation 469/2009/EC in response to this deficit?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Represer	ntatives of
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Favour	20,21%	20,11%	17,07%	17,65%	16,13%	31,75%	10,87%	-	18,18%	17,39%
Oppose	56,99%	57,54%	64,63%	66,67%	61,29%	41,27%	65,22%	50,00%	61,62%	63,04%
Impossible to say, no opinion	22,80%	22,35%	18,29%	15,69%	22,58%	26,98%	23,91%	50,00%	20,20%	19,57%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of law firm		Con University/re	npany, Associat search institution	ion, on is located	C	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Favour	20,21%	23,81%	34,15%	19,30%	21,95%	-	22,22%	42,11%	5,77%	11,76%	24,49%	13,43%	27,27%
Oppose	56,99%	57,14%	34,15%	59,65%	51,22%	100,00%	66,67%	15,79%	82,69%	70,59%	53,06%	68,66%	54,55%
Impossible to say, no opinion	22,80%	19,05%	31,71%	21,05%	26,83%	-	11,11%	42,11%	11,54%	17,65%	22,45%	17,91%	18,18%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

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Ouestion 37

It is sometimes said that there is insufficient investment in the development of some categories of orphan drugs. Would you favour or oppose changing Regulation 469/2009/EC in response to this deficit?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
Favour	20,21%	15,32%	28,79%			
Oppose	56,99%	62,10%	50,00%			
Impossible to say, no opinion	22,80%	22,58%	21,21%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Question 38
What changes would you propose in response to insufficient investment in the development of some categories of orphan drugs?

Base = all respondents who answered "Favour" Q37

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)		Originator	Generic			institution	companies	companies	
Base	39	36	14	9	5	20	5	-	18	8	
Persons who gave a concrete response (For the results on this question please see report		.=	== 4.00								
section "Verbatims")	48,72%	47,22%	57,14%	55,56%	60,00%	45,00%	40,00%	-	44,44%	50,00%	
Don't know	51,28%	52,78%	42,86%	44,44%	40,00%	55,00%	60,00%	-	55,56%	50,00%	

		Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	39	5	14	11	9	-	2	8	3	2	12	9	3
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	48,72%	40,00%	50,00%	54,55%	55,56%	-	50,00%	37,50%	100,00%	100,00%	50,00%	55,56%	66,67%
Don't know	51,28%	60,00%	50,00%	45,45%	44,44%	-	50,00%	62,50%	-	-	50,00%	44,44%	33,33%

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	39	19	19			
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")  Don't know	48,72% 51,28%	42,11% 57,89%	52,63% 47,37%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 39

Regulation 469/2009/EC was conceived in view of new molecules, new applications and new manufacturing methods.

The pharmaceutical industry is now increasingly investing in new formulations of existing drugs, new delivery systems and combination products. Taking this into account, would you favour or oppose amending the Regulation in this regard?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Representatives of		
	Total	\ later		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Favour	34,20%	34,08%	24,39%	23,53%	25,81%	57,14%	19,57%	50,00%	33,33%	23,91%	
Oppose	52,85%	54,19%	64,63%	66,67%	61,29%	33,33%	60,87%	-	57,58%	63,04%	
Impossible to say, no opinion	12,95%	11,73%	10,98%	9,80%	12,90%	9,52%	19,57%	50,00%	9,09%	13,04%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

		Type of law firm			npany, Associat search institution		Co	ompanies by siz	e	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Favour	34,20%	61,90%	53,66%	22,81%	19,51%	33,33%	22,22%	36,84%	17,31%	11,76%	32,65%	20,90%	27,27%
Oppose	52,85%	28,57%	36,59%	64,91%	65,85%	66,67%	66,67%	36,84%	76,92%	70,59%	55,10%	71,64%	36,36%
Impossible to say, no opinion	12,95%	9,52%	9,76%	12,28%	14,63%	-	11,11%	26,32%	5,77%	17,65%	12,24%	7,46%	36,36%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

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Ouestion 39

Regulation 469/2009/EC was conceived in view of new molecules, new applications and new manufacturing methods.

The pharmaceutical industry is now increasingly investing in new formulations of existing drugs, new delivery systems and combination products. Taking this into account, would you favour or oppose amending the Regulation in this regard?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attit current SF	
		positiv	negativ
Base	193	124	66
Favour	34,20%	29,84%	43,94%
Oppose	52,85%	58,87%	43,94%
Impossible to say, no opinion	12,95%	11,29%	12,12%
No response	-	-	-
Total	100,00%	100,00%	100,00%

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Question 40 Would you favour or oppose extending SPC protection to other fields of technology, such as medical devices, cosmetic products, or food products and food additives (both for humans and animals)?

### Base = all respondents

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
	202	partici- pants)	Total	Total Originator					companies	companies	
Base	203	189	89	51	31	63	46	5	99	46	
Favour	27,59%	25,93%	24,72%	23,53%	25,81%	39,68%	19,57%	-	27,27%	21,74%	
Oppose	36,45%	37,04%	28,09%	13,73%	58,06%	44,44%	39,13%	60,00%	19,19%	65,22%	
Impossible to say, no opinion	35,96%	37,04%	47,19%	62,75%	16,13%	15,87%	41,30%	40,00%	53,54%	13,04%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

	Type of law firm		Con University/re	npany, Associat search institution	tion, on is located	C	ompanies by siz	ze	Position a	company	Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	203	21	41	64	48	6	14	20	53	19	53	70	15
Favour	27,59%	47,62%	34,15%	18,75%	14,58%	33,33%	28,57%	35,00%	16,98%	26,32%	26,42%	21,43%	33,33%
Oppose	36,45%	47,62%	43,90%	37,50%	39,58%	66,67%	28,57%	45,00%	22,64%	21,05%	30,19%	30,00%	13,33%
Impossible to say, no opinion	35,96%	4,76%	21,95%	43,75%	45,83%	-	42,86%	20,00%	60,38%	52,63%	43,40%	48,57%	53,33%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 40 Would you favour or oppose extending SPC protection to other fields of technology, such as medical devices, cosmetic products, or food products and food additives (both for humans and animals)?

Base = all respondents

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	203	124	66
Favour	27,59%	30,65%	24,24%
Oppose	36,45%	25,81%	59,09%
Impossible to say, no opinion	35,96%	43,55%	16,67%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 41
To which types of products would you favour extending the current SPC protection?
(Multiple responses possible)

Base = all respondents who answered "Favour" Q40

		Total (without the			Type of st	akeholder			Represer	entatives of	
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Total Originator Generic				institution	companies	companies	
Base	56	49	22	12	8	25	9	-	27	10	
Medical devices	91,07%	93,88%	90,91%	100,00%	87,50%	92,00%	88,89%	-	92,59%	80,00%	
Cosmetic products	42,86%	48,98%	40,91%	25,00%	62,50%	44,00%	44,44%	-	40,74%	50,00%	
Food additives	37,50%	40,82%	31,82%	16,67%	50,00%	36,00%	55,56%	-	33,33%	40,00%	
Food products	33,93%	36,73%	22,73%	25,00%	25,00%	40,00%	44,44%	-	37,04%	30,00%	
Other	16,07%	16,33%	4,55%	8,33%	-	24,00%	22,22%	-	22,22%	-	
Sum of answers	221,43%	236,73%	190,91%	175,00%	225,00%	236,00%	255,56%	-	225,93%	200,00%	
No response	1,79%	-	-	-	-	-	11,11%	-	-	10,00%	

		Type of law firm		Con University/re	npany, Associat esearch institutio	tion, on is located	C	ompanies by siz	re	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	56	10	14	12	7	2	4	7	9	5	14	15	5
Medical devices	91,07%	80,00%	100,00%	91,67%	85,71%	100,00%	100,00%	85,71%	88,89%	100,00%	92,86%	86,67%	100,00%
Cosmetic products	42,86%	40,00%	50,00%	58,33%	71,43%	50,00%	25,00%	71,43%	33,33%	40,00%	42,86%	53,33%	20,00%
Food additives	37,50%	30,00%	42,86%	50,00%	71,43%	50,00%	25,00%	57,14%	22,22%	20,00%	35,71%	33,33%	40,00%
Food products	33,93%	30,00%	50,00%	33,33%	42,86%	-	50,00%	28,57%	11,11%	20,00%	28,57%	26,67%	20,00%
Other	16,07%	30,00%	21,43%	-	-	-	-	-	11,11%	-	7,14%	6,67%	-
Sum of answers	221,43%	210,00%	264,29%	233,33%	271,43%	200,00%	200,00%	242,86%	166,67%	180,00%	207,14%	206,67%	180,00%
No response	1,79%	-	-	-	-	-	-	-	-	-	-	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 41
To which types of products would you favour extending the current SPC protection?
(Multiple responses possible)

Base = all respondents who answered "Favour" Q40

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	56	38	16			
Medical devices	91,07%	94,74%	87,50%			
Cosmetic products	42,86%	44,74%	37,50%			
Food additives	37,50%	42,11%	25,00%			
Food products	33,93%	42,11%	18,75%			
Other	16,07%	15,79%	18,75%			
Sum of answers	221,43%	239,47%	187,50%			
No response	1,79%	2,63%	-			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Ouestion 42

Please comment on the pros and cons of extending SPC protection to other fields of technology, such as medical devices, cosmetic products, or food products and food additives (both for humans and animals)?

### Base = all respondents

		Total (without the later accepted partici-			Type of st	akeholder			Representatives of	
	Total			Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	203	189	89	51	31	63	46	5	99	46
Persons who gave a concrete response (For the results on this question please see report			05.450	<b>-0</b> -00/	0.1.700/					======
section "Verbatims")	72,41%	71,43%	65,17%	70,59%	64,52%	74,60%	84,78%	60,00%	72,73%	73,91%
Don't know	27,59%	28,57%	34,83%	29,41%	35,48%	25,40%	15,22%	40,00%	27,27%	26,09%

		Type of law firm		Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	203	21	41	64	48	6	14	20	53	19	53	70	15
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	72,41%	80,95%	70,73%	59,38%	56,25%	100,00%	50,00%	45,00%	75,47%	57,89%	66,04%	68,57%	46,67%
Don't know	27,59%	19,05%	29,27%	40,63%	43,75%	-	50,00%	55,00%	24,53%	42,11%	33,96%	31,43%	53,33%

	Total	General attitude towards current SPC system			
		positiv	negativ		
Base	203	124	66		
Persons who gave a concrete response (For the results on this question please see report					
section "Verbatims")	72,41%	73,39%	77,27%		
Don't know	27,59%	26,61%	22,73%		

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# Ouestion 43

Regulation 469/2009/EC does not define the concept of "active ingredient".

All in all, would you favour or oppose including a definition of "active ingredient" in Regulation 469/2009/EC?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Favour	44,04%	43,58%	41,46%	25,49%	67,74%	58,73%	28,26%	50,00%	26,26%	60,87%	
Oppose	45,60%	46,93%	50,00%	66,67%	22,58%	33,33%	56,52%	-	62,63%	30,43%	
Undecided, no opinion	9,84%	8,94%	8,54%	7,84%	9,68%	7,94%	13,04%	50,00%	11,11%	8,70%	
No response	0,52%	0,56%	-	-	-	-	2,17%	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

	Type of law firm			Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Favour	44,04%	66,67%	53,66%	49,12%	56,10%	50,00%	33,33%	84,21%	26,92%	35,29%	53,06%	37,31%	54,55%
Oppose	45,60%	28,57%	36,59%	40,35%	31,71%	33,33%	22,22%	15,79%	67,31%	52,94%	38,78%	53,73%	36,36%
Undecided, no opinion	9,84%	4,76%	9,76%	10,53%	12,20%	16,67%	44,44%	-	5,77%	11,76%	8,16%	8,96%	9,09%
No response	0,52%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 43

Regulation 469/2009/EC does not define the concept of "active ingredient".

All in all, would you favour or oppose including a definition of "active ingredient" in Regulation 469/2009/EC?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attit current SF	
		positiv	negativ
Base	193	124	66
Favour	44,04%	29,03%	71,21%
Oppose	45,60%	61,29%	18,18%
Undecided, no opinion	9,84%	8,87%	10,61%
No response	0,52%	0,81%	-
Total	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 44

Please read through the following proposed definition on the left side of the screen.

Prosposed defintion:

"An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/83/EC and Directive 2001/82/EC to which the SPC application refers."

In your view, would this definition of active ingredients provide legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Represer	tatives of
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Yes	25,91%	26,82%	23,17%	21,57%	25,81%	36,51%	17,39%	-	22,22%	28,26%
No	50,26%	50,84%	53,66%	64,71%	35,48%	41,27%	56,52%	50,00%	58,59%	34,78%
Impossible to say	23,32%	22,35%	23,17%	13,73%	38,71%	22,22%	23,91%	50,00%	19,19%	36,96%
No response	0,52%	-	-	-	-	-	2,17%	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Yes	25,91%	33,33%	36,59%	28,07%	29,27%	16,67%	33,33%	47,37%	13,46%	23,53%	24,49%	20,90%	36,36%
No	50,26%	52,38%	36,59%	45,61%	39,02%	50,00%	33,33%	21,05%	69,23%	58,82%	48,98%	58,21%	27,27%
Impossible to say	23,32%	14,29%	26,83%	26,32%	31,71%	33,33%	33,33%	31,58%	17,31%	17,65%	26,53%	20,90%	36,36%
No response	0,52%	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 44

Please read through the following proposed definition on the left side of the screen.

Prosposed defintion:

"An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/83/EC and Directive 2001/82/EC to which the SPC application refers."

In your view, would this definition of active ingredients provide legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude toward current SPC system			
		positiv	negativ		
Base	193	124			
Yes	25,91%	22,58%	30,30%		
No	50,26%	59,68%	34,85%		
Impossible to say	23,32%	17,74%	33,33%		
No response	0,52%	-	1,52%		
Total	100,00%	100,00% 100,00			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 44

Please read through the following proposed definition on the left side of the screen.

Prosposed defintion:

"An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/83/EC and Directive 2001/82/EC to which the SPC application refers."

In your view, would this definition of active ingredients provide legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

			Question 43	
	Total	Favour	Oppose	Undecided, no opinion
Base	193	85	88	19
Yes	25,91%	50,59%	4,55%	15,79%
No	50,26%	31,76%	75,00%	21,05%
Impossible to say	23,32%	17,65%	20,45%	57,89%
No response	0,52%	-	-	5,26%
Total	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 45

Regulation 1610/96/EC clarifies that "the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them".

Neither Regulation 1610/96/EC nor Regulation 469/2009/EC do clarify, however, under which conditions the derivative may be considered a new product that satisfies the requirement under Art. 3 of Regulation 1610/96/EC

Proposed clarification:

"The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless they differ significantly in properties with regard to safety and/or efficacy", see Art. 10(2)(b) Directive 2001/83/EC"

All in all, would you favour or oppose this clarification?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Favour	41,45%	39,66%	39,02%	29,41%	54,84%	50,79%	32,61%	50,00%	28,28%	52,17%	
Oppose	48,19%	50,28%	53,66%	66,67%	32,26%	36,51%	56,52%	-	60,61%	39,13%	
Undecided, no opinion	9,84%	9,50%	6,10%	3,92%	9,68%	12,70%	10,87%	50,00%	11,11%	6,52%	
No response	0,52%	0,56%	1,22%	-	3,23%	-	-	-	-	2,17%	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

		Type of	Type of law firm		Company, Association, University/research institution is located		Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Favour	41,45%	47,62%	51,22%	45,61%	48,78%	50,00%	77,78%	63,16%	23,08%	35,29%	42,86%	32,84%	63,64%
Oppose	48,19%	42,86%	34,15%	43,86%	46,34%	-	22,22%	31,58%	67,31%	47,06%	51,02%	61,19%	18,18%
Undecided, no opinion	9,84%	9,52%	14,63%	8,77%	4,88%	33,33%	-	5,26%	7,69%	17,65%	4,08%	4,48%	18,18%
No response	0,52%	-	-	1,75%	-	16,67%	-	-	1,92%	-	2,04%	1,49%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 45

Regulation 1610/96/EC clarifies that "the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them".

Neither Regulation 1610/96/EC nor Regulation 469/2009/EC do clarify, however, under which conditions the derivative may be considered a new product that satisfies the requirement under Art. 3 of Regulation 1610/96/EC

Proposed clarification:

"The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless they differ significantly in properties with regard to safety and/or efficacy", see Art. 10(2)(b) Directive 2001/83/EC"

All in all, would you favour or oppose this clarification?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attit current SF		
		positiv	negativ	
Base	193	124	66	
Favour	41,45%	33,87%	56,06%	
Oppose	48,19%	58,06%	31,82%	
Undecided, no opinion	9,84%	8,06%	10,61%	
No response	0,52%	-	1,52%	
Total	100,00%	100,00% 100,00		

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 46

Our next question pertains to the CJEU case law on Art. 3(a) and (b) of Regulation 469/2009/EC and Regulation 1610/96/EC:

According to the CJEU, a product is protected by the basic patent within the meaning of Art. 3(a) SPC Regulation when it is specified in the wording of the claims of the basic patent (see, for instance, decision C322/10 - Medeva).

In your opinion, to what extent does this case law provide a clear criterion for deciding on SPC applications and/or resolving legal disputes?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Represer	tatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
+2 = Clear criterion	21,24%	21,79%	34,15%	50,98%	6,45%	3,17%	23,91%	-	37,37%	6,52%
+1	17,10%	16,76%	23,17%	19,61%	29,03%	9,52%	15,22%	50,00%	16,16%	28,26%
0	15,54%	15,64%	9,76%	5,88%	16,13%	17,46%	21,74%	50,00%	12,12%	19,57%
-1	17,62%	17,88%	17,07%	13,73%	22,58%	20,63%	15,22%	-	12,12%	19,57%
-2 = Unclear criterion	28,50%	27,93%	15,85%	9,80%	25,81%	49,21%	23,91%	-	22,22%	26,09%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
+2 and +1	38,34%	38,55%	57,32%	70,59%	35,48%	12,70%	39,13%	50,00%	53,54%	34,78%
0	15,54%	15,64%	9,76%	5,88%	16,13%	17,46%	21,74%	50,00%	12,12%	19,57%
-1 and -2	46,11%	45,81%	32,93%	23,53%	48,39%	69,84%	39,13%	-	34,34%	45,65%
Mean value	-0,15	-0,13	0,43	0,88	-0,32	-1,03	0,00	0,50	0,34	-0,30

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 46

Our next question pertains to the CJEU case law on Art. 3(a) and (b) of Regulation 469/2009/EC and Regulation 1610/96/EC:

According to the CJEU, a product is protected by the basic patent within the meaning of Art. 3(a) SPC Regulation when it is specified in the wording of the claims of the basic patent (see, for instance, decision C322/10 - Medeva).

In your opinion, to what extent does this case law provide a clear criterion for deciding on SPC applications and/or resolving legal disputes?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of law firm		Con University/re	npany, Associatesearch institution	ion, on is located	С	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
+2 = Clear criterion	21,24%	9,52%	-	24,56%	24,39%	-	11,11%	15,79%	44,23%	52,94%	28,57%	37,31%	18,18%
+1	17,10%	14,29%	7,32%	22,81%	21,95%	33,33%	22,22%	26,32%	23,08%	23,53%	22,45%	25,37%	9,09%
0	15,54%	14,29%	17,07%	14,04%	17,07%	-	11,11%	21,05%	5,77%	11,76%	12,24%	10,45%	9,09%
-1	17,62%	19,05%	21,95%	19,30%	21,95%	33,33%	33,33%	21,05%	11,54%	5,88%	18,37%	11,94%	36,36%
-2 = Unclear criterion	28,50%	42,86%	53,66%	19,30%	14,63%	33,33%	22,22%	15,79%	15,38%	5,88%	18,37%	14,93%	27,27%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
+2 and +1	38,34%	23,81%	7,32%	47,37%	46,34%	33,33%	33,33%	42,11%	67,31%	76,47%	51,02%	62,69%	27,27%
0	15,54%	14,29%	17,07%	14,04%	17,07%	-	11,11%	21,05%	5,77%	11,76%	12,24%	10,45%	9,09%
-1 and -2	46,11%	61,90%	75,61%	38,60%	36,59%	66,67%	55,56%	36,84%	26,92%	11,76%	36,73%	26,87%	63,64%
Mean value	-0,15	-0,71	-1,22	0,14	0,20	-0,67	-0,33	0,05	0,69	1,12	0,24	0,58	-0,45

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 46

Our next question pertains to the CJEU case law on Art. 3(a) and (b) of Regulation 469/2009/EC and Regulation 1610/96/EC:

According to the CJEU, a product is protected by the basic patent within the meaning of Art. 3(a) SPC Regulation when it is specified in the wording of the claims of the basic patent (see, for instance, decision C322/10 - Medeva).

In your opinion, to what extent does this case law provide a clear criterion for deciding on SPC applications and/or resolving legal disputes?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
+2 = Clear criterion	21,24%	31,45%	3,03%			
+1	17,10%	17,74%	16,67%			
0	15,54%	14,52%	16,67%			
-1	17,62%	14,52%	22,73%			
-2 = Unclear criterion	28,50%	21,77%	40,91%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
+2 and +1	38,34%	49,19%	19,70%			
0	15,54%	14,52%	16,67%			
-1 and -2	46,11%	36,29%	63,64%			
Mean value	-0,15	0,23	-0,82			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 47

Please indicate the extent to which you agree or disagree with the following statement:

"According to the case law of the CJEU, the fact that the product falls within the scope of protection of one patent claim of the basic patent within the meaning of Art. 69 EPC

(or any domestic provision corresponding to Art. 69 EPC) is a necessary but not sufficient requirement to consider a product as protected by the basic patent within the meaning of Art. 3(a) of Regulation 469/2009/EC"

Base = all respondents who answered "unclear criterion" (-1 or -2) in Q46

		Total (without the			Type of st	akeholder			Representatives of		
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	89	82	27	12	15	44	18	-	34	21	
Strongly agree	13,48%	13,41%	11,11%	-	20,00%	15,91%	11,11%	-	8,82%	19,05%	
Agree	43,82%	45,12%	40,74%	50,00%	33,33%	47,73%	38,89%	-	47,06%	42,86%	
Disagree	17,98%	19,51%	11,11%	8,33%	13,33%	25,00%	11,11%	-	20,59%	9,52%	
Strongly disagree	10,11%	8,54%	7,41%	16,67%	-	9,09%	16,67%	-	14,71%	-	
Impossible to say	14,61%	13,41%	29,63%	25,00%	33,33%	2,27%	22,22%	-	8,82%	28,57%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	100,00%	100,00%	
Strongly agree, Agree	57,30%	58,54%	51,85%	50,00%	53,33%	63,64%	50,00%	-	55,88%	61,90%	
Disagree, Strongly disagree	28,09%	28,05%	18,52%	25,00%	13,33%	34,09%	27,78%	-	35,29%	9,52%	

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 47

Please indicate the extent to which you agree or disagree with the following statement:

"According to the case law of the CJEU, the fact that the product falls within the scope of protection of one patent claim of the basic patent within the meaning of Art. 69 EPC

(or any domestic provision corresponding to Art. 69 EPC) is a necessary but not sufficient requirement to consider a product as protected by the basic patent within the meaning of Art. 3(a) of Regulation 469/2009/EC"

Base = all respondents who answered "unclear criterion" (-1 or -2) in Q46

		Type of	law firm	Company, Association, University/research institution is located			С	ompanies by siz	re	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	13	31	22	15	4	5	7	14	2	18	18	7
Strongly agree	13,48%	7,69%	19,35%	9,09%	6,67%	-	20,00%	-	7,14%	-	16,67%	11,11%	-
Agree	43,82%	46,15%	48,39%	45,45%	33,33%	75,00%	40,00%	28,57%	50,00%	50,00%	33,33%	38,89%	57,14%
Disagree	17,98%	30,77%	22,58%	13,64%	20,00%	-	20,00%	28,57%	-	-	16,67%	11,11%	-
Strongly disagree	10,11%	15,38%	6,45%	4,55%	6,67%	-	-	-	14,29%	-	11,11%	11,11%	-
Impossible to say	14,61%	-	3,23%	27,27%	33,33%	25,00%	20,00%	42,86%	28,57%	50,00%	22,22%	27,78%	42,86%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Strongly agree, Agree	57,30%	53,85%	67,74%	54,55%	40,00%	75,00%	60,00%	28,57%	57,14%	50,00%	50,00%	50,00%	57,14%
Disagree, Strongly disagree	28,09%	46,15%	29,03%	18,18%	26,67%	-	20,00%	28,57%	14,29%	-	27,78%	22,22%	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 47

Please indicate the extent to which you agree or disagree with the following statement:
"According to the case law of the CJEU, the fact that the product falls within the scope of protection of one patent claim

of the basic patent within the meaning of Art. 69 EPC (or any domestic provision corresponding to Art. 69 EPC) is a necessary but not sufficient requirement to consider a product as protected by the basic patent within the meaning of Art. 3(a) of Regulation 469/2009/EC"

Base = all respondents who answered "unclear criterion" (-1 or -2) in Q46

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	89	45	42			
Strongly agree	13,48%	13,33%	14,29%			
Agree	43,82%	37,78%	50,00%			
Disagree	17,98%	24,44%	11,90%			
Strongly disagree	10,11%	11,11%	9,52%			
Impossible to say	14,61%	13,33%	14,29%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
Strongly agree, Agree	57,30%	51,11%	64,29%			
Disagree, Strongly disagree	28,09%	35,56%	21,43%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# Question 48

When it comes to Art. 3(a) of Regulation 469/2009/EC, and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Represer	itatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
A new paragraph in the Regulations with the following wording: "The product is protected by a basic patent in force when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC and corresponding national provisions and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed." According to this, the SPC may only be granted for subject matter to which the basic patent may be limited without violating Art. 123(2) EPC or the corresponding national provisions	11,92%	12,29%	9,76%	5,88%	16,13%	15,87%	8,70%	50,00%	8,08%	13,04%
A new paragraph with the following wording: "The product is protected when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC or the corresponding national provisions." This would be an infringement test.	20,73%	20,67%	13,41%	15,69%	9,68%	39,68%	8,70%	<u>-</u>	20,20%	8,70%
A new paragraph providing a "core inventive advance test" (as in UK case law) whereby the subject matter of the SPC is protected by the basic patent when two requirements are cumulatively met: it falls under the scope of protection of the patent and it represents the core inventive advance of the invention	18,13%	17,88%	19,51%	5,88%	41,94%	19,05%	15,22%	_	6,06%	43,48%
No amendment of Art. 3(a) of Regulation 469/2009/EC is needed	37,82%	39,11%	43,90%	62,75%	12,90%	15,87%	58,70%	_	55,56%	19,57%
No opinion, impossible to say	10,88%	9,50%	12,20%	9,80%	16,13%	9,52%	8,70%	50,00%	10,10%	13,04%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Ouestion 48

When it comes to Art. 3(a) of Regulation 469/2009/EC, and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of	law firm		npany, Associat esearch institution		C	ompanies by siz	ze	Position a	t company	Scope of activ	company
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
A new paragraph in the Regulations with the following wording: "The product is protected by a basic patent in force when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC and corresponding national provisions and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed." According to this, the SPC may only be granted for subject matter to which the basic patent may be limited without violating Art. 123(2) EPC or the corresponding national provisions  A new paragraph with the following wording: "The product	11,92%	19,05%	14,63%	12,28%	12,20%	16,67%	11,11%	26,32%	3,85%	-	14,29%	5,97%	27,27%
is protected when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC or the corresponding national provisions." This would be an infringement test.	20,73%	42,86%	36,59%	15,79%	14,63%	-	-	26,32%	11,54%	17,65%	14,29%	13,43%	18,18%
A new paragraph providing a "core inventive advance test" (as in UK case law) whereby the subject matter of the SPC is protected by the basic patent when two requirements are cumulatively met: it falls under the scope of protection of the patent and it represents the core inventive advance of the invention	18,13%	9,52%	24,39%	24,56%	21,95%	83,33%	11,11%	21,05%	19,23%	11,76%	24,49%	19,40%	18,18%
No amendment of Art. 3(a) of Regulation 469/2009/EC is needed	37,82%	23,81%	12,20%	33,33%	34,15%	-	22,22%	15,79%	57,69%	58,82%	34,69%	49,25%	18,18%
No opinion, impossible to say	10,88%	4,76%	12,20%	12,28%	14,63%	-	44,44%	10,53%	7,69%	11,76%	12,24%	10,45%	18,18%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 48
When it comes to Art. 3(a) of Regulation 469/2009/EC, and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	193	124	66
A new paragraph in the Regulations with the following wording: "The product is protected by a basic patent in force when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC and corresponding national provisions and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed." According to this, the SPC may only be granted for subject matter to which the basic patent may be limited without violating Art. 123(2) EPC or the corresponding national provisions	11,92%	8,87%	16,67%
A new paragraph with the following wording: "The product is protected when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC or the corresponding national provisions." This would be an infringement test.	20,73%	18,55%	25,76%
A new paragraph providing a "core inventive advance test" (as in UK case law) whereby the subject matter of the SPC is protected by the basic patent when two requirements are cumulatively met: - it falls under the scope of protection of the patent and - it represents the core inventive advance of the invention	18,13%	9,68%	33,33%
No amendment of Art. 3(a) of Regulation 469/2009/EC is needed	37,82%	54,84%	7,58%
No opinion, impossible to say	10,88%	8,06%	15,15%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

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Question 48
When it comes to Art. 3(a) of Regulation 469/2009/EC, and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the				Represer	ntatives of				
	Total	later accepted partici-	later Company				Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
No response	0,52%	0,56%	1,22%	-	3,23%	-	-	-	-	2,17%	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 48

When it comes to Art. 3(a) of Regulation 469/2009/EC, and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of	law firm	Company, Association, University/research institution is located			Companies by size			Position at	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
No response	0,52%	-	-	1,75%	2,44%	-	11,11%	-	-	-	-	1,49%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 48
When it comes to Art. 3(a) of Regulation 469/2009/EC, and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total		ude towards PC system
		positiv	negativ
Base	193	124	66
No response	0,52%	-	1,52%
Total	100,00%	100,00%	100,00%

# Ouestion 49

Our next questions refer to variations of marketing authorisations as described in Regulation 1234/2008/EC.

In your view, should all variations of a marketing authorisation constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted		Company		. Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	145	136	82	51	31	63	-	-	81	37	
Yes	10,34%	10,29%	7,32%	7,84%	6,45%	14,29%	-	-	8,64%	5,41%	
No	71,72%	73,53%	81,71%	76,47%	90,32%	58,73%	-	-	69,14%	89,19%	
No opinion	16,55%	14,71%	9,76%	15,69%	-	25,40%	-	-	20,99%	2,70%	
No response	1,38%	1,47%	1,22%	-	3,23%	1,59%	-	-	1,23%	2,70%	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Yes	10,34%	14,29%	14,63%	8,77%	9,76%	-	22,22%	15,79%	1,92%	5,88%	10,20%	7,46%	9,09%
No	71,72%	71,43%	51,22%	78,95%	75,61%	100,00%	55,56%	63,16%	92,31%	88,24%	77,55%	85,07%	72,73%
No opinion	16,55%	9,52%	34,15%	12,28%	14,63%	-	22,22%	21,05%	3,85%	5,88%	12,24%	5,97%	18,18%
No response	1,38%	4,76%	-	-	-	-	-	-	1,92%	-	-	1,49%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 49

Our next questions refer to variations of marketing authorisations as described in Regulation 1234/2008/EC.

In your view, should all variations of a marketing authorisation constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	91	53			
Yes	10,34%	10,99%	9,43%			
No	71,72%	72,53%	71,70%			
No opinion	16,55%	15,38%	16,98%			
No response	1,38%	1,10%	1,89%			
Total	100,00%	100,00%	100,00%			

# Ouestion 50

In your opinion, should changes that require an extension of the marketing authorisation be considered to be a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total		Representatives of						
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	145	136	82	51	31	63	-	-	81	37
Yes	19,31%	19,12%	12,20%	13,73%	9,68%	28,57%	-	-	17,28%	10,81%
No	60,00%	62,50%	73,17%	68,63%	80,65%	42,86%	-	-	55,56%	78,38%
No opinion	18,62%	16,18%	12,20%	15,69%	6,45%	26,98%	-	-	24,69%	8,11%
No response	2,07%	2,21%	2,44%	1,96%	3,23%	1,59%	-	-	2,47%	2,70%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Yes	19,31%	33,33%	24,39%	10,53%	12,20%	-	33,33%	15,79%	7,69%	11,76%	12,24%	11,94%	9,09%
No	60,00%	33,33%	48,78%	77,19%	75,61%	100,00%	44,44%	68,42%	78,85%	76,47%	73,47%	74,63%	72,73%
No opinion	18,62%	28,57%	26,83%	10,53%	12,20%	-	22,22%	15,79%	9,62%	11,76%	14,29%	10,45%	18,18%
No response	2,07%	4,76%	-	1,75%	-	-	-	-	3,85%	-	-	2,99%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 50

In your opinion, should changes that require an extension of the marketing authorisation be considered to be a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	145	91	53
Yes	19,31%	20,88%	16,98%
No	60,00%	56,04%	67,92%
No opinion	18,62%	20,88%	13,21%
No response	2,07%	2,20%	1,89%
Total	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 50

In your opinion, should changes that require an extension of the marketing authorisation be considered to be a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total		Question 49	
	Total	Yes	No	No opinion
Base	145	15	104	24
Yes	19,31%	60,00%	13,46%	20,83%
No	60,00%	20,00%	78,85%	8,33%
No opinion	18,62%	20,00%	6,73%	70,83%
No response	2,07%	-	0,96%	-
Total	100,00%	100,00%	100,00%	100,00%

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Ouestion 51

Regulation 1234/2008/EC refers to three types of variations which have different implications depending on the likely

impact of the change on the quality, safety or efficacy of the medicinal product.

This includes "type II variations", that is, major variations that do not constitute an extension and which may have a significant impact "on the quality, safety or efficacy" of the medicinal product concerned.

In your view, should any "type II variation" constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted	Company		Law firm	Association	University/ Research	Originator	Generic		
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	145	136	82	51	31	63	-	-	81	37	
Yes	15,86%	15,44%	6,10%	9,80%	-	28,57%	-	-	13,58%	5,41%	
No	59,31%	60,29%	75,61%	66,67%	90,32%	38,10%	-	-	53,09%	86,49%	
No opinion	22,76%	22,06%	15,85%	21,57%	6,45%	31,75%	-	-	30,86%	5,41%	
No response	2,07%	2,21%	2,44%	1,96%	3,23%	1,59%	-	-	2,47%	2,70%	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

		Type of	law firm		Company, Association, rersity/research institution is located Companies by size		Position a	t company	Scope of company activities				
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Yes	15,86%	33,33%	24,39%	5,26%	7,32%	-	22,22%	5,26%	3,85%	5,88%	6,12%	5,97%	9,09%
No	59,31%	33,33%	41,46%	77,19%	75,61%	100,00%	55,56%	63,16%	82,69%	88,24%	69,39%	79,10%	63,64%
No opinion	22,76%	33,33%	31,71%	15,79%	17,07%	-	22,22%	31,58%	9,62%	5,88%	22,45%	11,94%	27,27%
No response	2,07%	-	2,44%	1,75%	-	-	-	-	3,85%	-	2,04%	2,99%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 51

Regulation 1234/2008/EC refers to three types of variations which have different implications depending on the likely impact of the change on the quality, safety or efficacy of the medicinal product.

This includes "type II variations", that is, major variations that do not constitute an extension and which may have a significant impact "on the quality, safety or efficacy" of the medicinal product concerned.

In your view, should any "type II variation" constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attit current SF	
		positiv	negativ
Base	145	91	53
Yes	15,86%	16,48%	15,09%
No	59,31%	56,04%	66,04%
No opinion	22,76%	25,27%	16,98%
No response	2,07%	2,20%	1,89%
Total	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 51

Regulation 1234/2008/EC refers to three types of variations which have different implications depending on the likely impact of the change on the quality, safety or efficacy of the medicinal product.

This includes "type II variations", that is, major variations that do not constitute an extension and which may have a significant impact "on the quality, safety or efficacy" of the medicinal product concerned.

In your view, should any "type II variation" constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC or not?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total		Question 49	
	Total	Yes	No	No opinion
Base	145	15	104	24
Yes	15,86%	53,33%	9,62%	16,67%
No	59,31%	13,33%	77,88%	8,33%
No opinion	22,76%	26,67%	10,58%	75,00%
No response	2,07%	6,67%	1,92%	-
Total	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 52

In the decision 'Neurim C-130/11' the CJEU set out the conditions under which a "different application of the same product" meets the requirements for SPC eligibility. Do you agree with this case law?

Base = all law firm or patent law firm

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	63	58	-	-	-	63	-	-	30	6	
Yes	66,67%	67,24%	-	-	-	66,67%	-	-	76,67%	66,67%	
No	12,70%	12,07%	-	-	-	12,70%	-	-	6,67%	33,33%	
No opinion	20,63%	20,69%	-	-	-	20,63%	-	-	16,67%	-	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	-	-	-	100,00%	-	-	100,00%	100,00%	

		Type of	law firm	Con University/re	npany, Associat esearch institution	tion, on is located	Companies by size		Position a	t company	Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	63	21	41	-	-	-	-	-	-	-	-	-	-
Yes	66,67%	71,43%	65,85%	-	-	-	-	-	-	-	-	-	-
No	12,70%	14,29%	12,20%	-	-	-	-	-	-	-	-	-	-
No opinion	20,63%	14,29%	21,95%	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 52

In the decision 'Neurim C-130/11' the CJEU set out the conditions under which a "different application of the same product" meets the requirements for SPC eligibility. Do you agree with this case law?

Base = all law firm or patent law firm

	Total		tude towards PC system		
		positiv	negativ		
Base	63	41	22		
Yes	66,67%	75,61%	50,00%		
No	12,70%	7,32%	22,73%		
No opinion	20,63%	17,07%	27,27%		
No response	-	-	-		
Total	100,00%	100,00%	100,00%		

Would you consider a type II marketing authorisation variation (Art. 2 para 3 of Regulation 1234/2008) as sufficient to meet the requirements for a "different application of the same product", as set out in the Neurim decision ('Neurim C-130/11')?

### Base = all law firm or patent law firm

		Total			Type of st	akeholder			Representatives of	
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		Zaw iiiii 7.6566iati6ii		companies	companies
Base	63	58	-	-	-	63	-	-	30	6
Yes, sufficient	30,16%	29,31%	-	-	-	30,16%	-	-	33,33%	33,33%
No, not sufficient	28,57%	29,31%	-	-	-	28,57%	-	-	20,00%	66,67%
No opinion	41,27%	41,38%	-	-	-	41,27%	-	-	46,67%	-
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	-	-	-	100,00%	-	-	100,00%	100,00%

		Type of	law firm	Con University/re	npany, Associa esearch institution	tion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of activ	company ities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	63	21	41	-	-	-	-	-	-	-	-	-	-
Yes, sufficient	30,16%	47,62%	21,95%	-	-	-	-	-	-	-	-	-	-
No, not sufficient	28,57%	23,81%	31,71%	-	-	-	-	-	-	-	-	-	-
No opinion	41,27%	28,57%	46,34%	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 53

Would you consider a type II marketing authorisation variation (Art. 2 para 3 of Regulation 1234/2008) as sufficient to meet the requirements for a "different application of the same product", as set out in the Neurim decision ('Neurim C-130/11')?

Base = all law firm or patent law firm

	Total		ude towards PC system
		positiv	negativ
Base	63	41	22
Yes, sufficient	30,16%	29,27%	31,82%
No, not sufficient	28,57%	24,39%	36,36%
No opinion	41,27%	46,34%	31,82%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Our next question is about the possibility-by filing an SPC application-of referring to a third-party marketing authorisation without obtaining the consent of that third party. In your experience, to what extent does that lead to practical problems for the holder of the authorisation in obtaining a license from the patent holder?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total (without the			Type of st	akeholder			Representatives of	
	Total	` later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	145	136	82	51	31	63	-	-	81	37
To a great extent	18,62%	19,12%	15,85%	15,69%	16,13%	22,22%	-	-	13,58%	21,62%
To a moderate extent	17,93%	18,38%	15,85%	9,80%	25,81%	20,63%	-	-	18,52%	21,62%
To a lesser extent	6,90%	5,88%	2,44%	3,92%	-	12,70%	-	-	8,64%	-
Rarely/not at all	24,14%	25,00%	34,15%	54,90%	-	11,11%	-	-	37,04%	-
Don't know, no opinion	32,41%	31,62%	31,71%	15,69%	58,06%	33,33%	-	-	22,22%	56,76%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%
To a great extent, To a moderate extent	36,55%	37,50%	31,71%	25,49%	41,94%	42,86%	-	-	32,10%	43,24%
To a lesser extent, Rarely/not at all	31,03%	30,88%	36,59%	58,82%	-	23,81%	-	-	45,68%	-

Our next question is about the possibility-by filing an SPC application-of referring to a third-party marketing authorisation without obtaining the consent of that third party. In your experience, to what extent does that lead to practical problems for the holder of the authorisation in obtaining a license from the patent holder?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Type of	law firm	Con University/re	npany, Associa esearch institution	tion, on is located	C	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
To a great extent	18,62%	19,05%	24,39%	17,54%	14,63%	33,33%	11,11%	26,32%	13,46%	5,88%	20,41%	14,93%	27,27%
To a moderate extent	17,93%	28,57%	14,63%	19,30%	17,07%	50,00%	33,33%	10,53%	15,38%	23,53%	14,29%	14,93%	18,18%
To a lesser extent	6,90%	9,52%	14,63%	1,75%	2,44%	-	11,11%	-	1,92%	-	4,08%	1,49%	9,09%
Rarely/not at all	24,14%	23,81%	4,88%	24,56%	21,95%	-	-	-	53,85%	35,29%	28,57%	40,30%	9,09%
Don't know, no opinion	32,41%	19,05%	41,46%	36,84%	43,90%	16,67%	44,44%	63,16%	15,38%	35,29%	32,65%	28,36%	36,36%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
To a great extent, To a moderate extent	36,55%	47,62%	39,02%	36,84%	31,71%	83,33%	44,44%	36,84%	28,85%	29,41%	34,69%	29,85%	45,45%
To a lesser extent, Rarely/not at all	31,03%	33,33%	19,51%	26,32%	24,39%	-	11,11%	-	55,77%	35,29%	32,65%	41,79%	18,18%

Our next question is about the possibility-by filing an SPC application-of referring to a third-party marketing authorisation without obtaining the consent of that third party. In your experience, to what extent does that lead to practical problems for the holder of the authorisation in obtaining a license from the patent holder?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	91	53			
To a great extent	18,62%	14,29%	26,42%			
To a moderate extent	17,93%	15,38%	22,64%			
To a lesser extent	6,90%	6,59%	7,55%			
Rarely/not at all	24,14%	36,26%	3,77%			
Don't know, no opinion	32,41%	27,47%	39,62%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			
To a great extent, To a moderate extent	36,55%	29,67%	49,06%			
To a lesser extent, Rarely/not at all	31,03%	42,86%	11,32%			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 55
The case law of the CJEU is currently not clear with respect to third-party marketing authorisations:
Which of the following clarifications would you prefer?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total (without the			Type of st	akeholder			Represer	ntatives of
	Total	` later accepted		Company		. Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	145	136	82	51	31	63	-	-	81	37
The applicant can refer to a third-party marketing authorisation whether the holder of the marketing authorisation agrees to it or not and with no formalities.  The applicant may only refer to a third-party marketing authorisation when the third party is in agreement and evidence of his/her consent is	21,38%	19,85%	12,20%	7,84%	19,35%	33,33%	-	-	19,75%	21,62%
included in the application.	44,14%	46,32%	37,80%	29,41%	51,61%	52,38%	-	-	34,57%	54,05%
No opinion	22,07%	20,59%	30,49%	35,29%	22,58%	11,11%	-	-	27,16%	18,92%
No response	12,41%	13,24%	19,51%	27,45%	6,45%	3,17%	-	-	18,52%	5,41%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 55
The case law of the CJEU is currently not clear with respect to third-party marketing authorisations:
Which of the following clarifications would you prefer?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Type of	law firm		npany, Associat esearch institutio		Co	ompanies by siz	е	Position at	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
The applicant can refer to a third-party marketing authorisation whether the holder of the marketing authorisation agrees to it or not and with no formalities.  The applicant may only refer to a third-party marketing authorisation when the third party is in agreement and evidence of his/her consent is	21,38%	33,33%	31,71%	15,79%	17,07%	33,33%	22,22%	26,32%	5,77%	11,76%	16,33%	8,96%	27,27%
included in the application.	44,14%	52,38%	53,66%	47,37%	46,34%	66,67%	55,56%	36,84%	36,54%	41,18%	38,78%	37,31%	45,45%
No opinion	22,07%	9,52%	12,20%	22,81%	19,51%	-	22,22%	31,58%	28,85%	29,41%	26,53%	29,85%	27,27%
No response	12,41%	4,76%	2,44%	14,04%	17,07%	-	-	5,26%	28,85%	17,65%	18,37%	23,88%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 55
The case law of the CJEU is currently not clear with respect to third-party marketing authorisations: Which of the following clarifications would you prefer?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attit current SF	
		positiv	negativ
Base	145	91	53
The applicant can refer to a third-party marketing authorisation whether the holder of the marketing authorisation agrees to it or not and with no formalities.	21,38%	19,78%	22,64%
The applicant may only refer to a third-party marketing authorisation when the third party is in agreement and evidence of his/her consent is included in the application.	44,14%	36,26%	58,49%
No opinion	22,07%	25,27%	16,98%
No response	12,41%	18,68%	1,89%
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 55
The case law of the CJEU is currently not clear with respect to third-party marketing authorisations: Which of the following clarifications would you prefer?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

				Question 54		
	Total	To a great extent	To a moderate extent	To a lesser extent	Rarely/not at all	Don't know, no opinion
Base	145	27	26	10	35	47
The applicant can refer to a third-party marketing authorisation whether the holder of the marketing authorisation agrees to it or not and with no formalities.  The applicant may only refer to a third-party marketing authorisation when the third	21,38%	11,11%	30,77%	70,00%	11,43%	19,15%
party is in agreement and evidence of his/her consent is included in the application.	44,14%	81,48%	57,69%	20,00%	14,29%	42,55%
No opinion	22,07%	3,70%	3,85%	10,00%	34,29%	36,17%
No response	12,41%	3,70%	7,69%	-	40,00%	2,13%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 56

In Europe it is not possible to obtain an SPC if the patent expires before the marketing authorisation has been granted.

By contrast, in the United States it is possible to obtain a patent extension even if the patent expires before the marketing authorisation has been granted.

The patent holder can in fact file an application for an interim extension before the expiration date of the patent.

In practice, do you favour amending the EU Regulations in this regard?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm or professional association

		Total			Type of st	akeholder			Representatives of	
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total Originator		Generic			institution	companies	companies
Base	154	145	82	51	31	63	9	-	81	37
Yes	38,31%	37,93%	25,61%	29,41%	19,35%	53,97%	44,44%	-	38,27%	24,32%
No	53,90%	54,48%	69,51%	64,71%	77,42%	34,92%	44,44%	-	50,62%	70,27%
No opinion	7,79%	7,59%	4,88%	5,88%	3,23%	11,11%	11,11%	-	11,11%	5,41%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	100,00%	100,00%

		Type of	law firm	Company, Association, University/research institution is located			С	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	154	21	41	57	41	6	9	19	52	17	49	67	11
Yes	38,31%	52,38%	56,10%	31,58%	34,15%	-	66,67%	47,37%	11,54%	23,53%	30,61%	19,40%	54,55%
No	53,90%	38,10%	31,71%	64,91%	63,41%	100,00%	33,33%	42,11%	84,62%	64,71%	65,31%	76,12%	36,36%
No opinion	7,79%	9,52%	12,20%	3,51%	2,44%	-	-	10,53%	3,85%	11,76%	4,08%	4,48%	9,09%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 56

In Europe it is not possible to obtain an SPC if the patent expires before the marketing authorisation has been granted.

By contrast, in the United States it is possible to obtain a patent extension even if the patent expires before the marketing authorisation has been granted.

The patent holder can in fact file an application for an interim extension before the expiration date of the patent.

In practice, do you favour amending the EU Regulations in this regard?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm or professional association

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	154	96	56
Yes	38,31%	36,46%	41,07%
No	53,90%	56,25%	51,79%
No opinion	7,79%	7,29%	7,14%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself. In practice, do you favour amending the EU Regulations in this regard?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm or professional association

		Total			Type of st	akeholder			Represer	ntatives of	
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	154	145	82	51	31	63	9	-	81	37	
Yes	32,47%	31,72%	24,39%	27,45%	19,35%	44,44%	22,22%	-	34,57%	21,62%	
No	57,79%	58,62%	71,95%	70,59%	74,19%	39,68%	55,56%	-	56,79%	70,27%	
No opinion	9,09%	8,97%	3,66%	1,96%	6,45%	14,29%	22,22%	-	8,64%	8,11%	
No response	0,65%	0,69%	-	-	-	1,59%	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	100,00%	100,00%	

		Type of	law firm	Con University/re	npany, Associat esearch institution	tion, on is located	Co	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	154	21	41	57	41	6	9	19	52	17	49	67	11
Yes	32,47%	42,86%	46,34%	31,58%	36,59%	-	77,78%	47,37%	7,69%	23,53%	26,53%	17,91%	54,55%
No	57,79%	42,86%	36,59%	64,91%	60,98%	83,33%	22,22%	47,37%	88,46%	70,59%	69,39%	77,61%	45,45%
No opinion	9,09%	9,52%	17,07%	3,51%	2,44%	16,67%	-	5,26%	3,85%	5,88%	4,08%	4,48%	-
No response	0,65%	4,76%	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 57

In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself. In practice, do you favour amending the EU Regulations in this regard?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm or professional association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	154	96	56			
Yes	32,47%	30,21%	35,71%			
No	57,79%	64,58%	48,21%			
No opinion	9,09%	4,17%	16,07%			
No response	0,65%	1,04%	-			
Total	100,00%	100,00%	100,00%			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Ouestion 58

Patent claims are statements that define the matter for which protection is sought in terms of the technical features of the invention. So far, Regulation 469/2009/EC does not seem to provide that such statements should be included in the SPC application.

If the subject matter for which protection is sought had to be specified already in the SPC application in a form similar to patent claims:

Do you think that this would facilitate the examination procedure or, on the contrary, make it more difficult, or do you think it would make no difference?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total			Type of st	akeholder			Represer	ntatives of	
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator Generic			institution	companies	companies		
Base	145	136	82	51	31	63	-	-	81	37	
Facilitate	24,83%	24,26%	23,17%	13,73%	38,71%	26,98%	-	-	14,81%	37,84%	
Make it more difficult	46,21%	47,79%	53,66%	72,55%	22,58%	36,51%	-	-	61,73%	21,62%	
Would make no difference	14,48%	14,71%	8,54%	3,92%	16,13%	22,22%	-	-	11,11%	16,22%	
No opinion	14,48%	13,24%	14,63%	9,80%	22,58%	14,29%	-	-	12,35%	24,32%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

	Type of law firm			Company, Association, University/research institution is located			C	ompanies by siz	e	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Facilitate	24,83%	38,10%	19,51%	28,07%	26,83%	66,67%	44,44%	26,32%	19,23%	11,76%	28,57%	20,90%	27,27%
Make it more difficult	46,21%	38,10%	36,59%	45,61%	48,78%	-	11,11%	31,58%	69,23%	58,82%	53,06%	59,70%	27,27%
Would make no difference	14,48%	14,29%	26,83%	12,28%	7,32%	33,33%	22,22%	10,53%	5,77%	11,76%	4,08%	7,46%	18,18%
No opinion	14,48%	9,52%	17,07%	14,04%	17,07%	-	22,22%	31,58%	5,77%	17,65%	14,29%	11,94%	27,27%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 58

Patent claims are statements that define the matter for which protection is sought in terms of the technical features of the invention. So far, Regulation 469/2009/EC does not seem to provide that such statements should be included in the SPC application.

If the subject matter for which protection is sought had to be specified already in the SPC application in a form similar to patent claims:

Do you think that this would facilitate the examination procedure or, on the contrary, make it more difficult, or do you think it would make no difference?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attit current SF	
		positiv	negativ
Base	145	91	53
Facilitate	24,83%	19,78%	33,96%
Make it more difficult	46,21%	58,24%	26,42%
Would make no difference	14,48%	9,89%	22,64%
No opinion	14,48%	12,09%	16,98%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Question 59
Which of the following measures would you expect to have a positive impact? Please mark all applicable measures. (Multiple responses possible)

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total (without the			Type of st	akeholder			Represer	tatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	145	136	82	51	31	63	-	-	81	37
If the procedures for granting SPCs were harmonised within the EU	87,59%	87,50%	90,24%	92,16%	87,10%	84,13%	-	<u>-</u>	87,65%	89,19%
If third parties had the right to file observations like in proceedings before the EPO under Art. 115 EPC	41,38%	41,91%	37,80%	13,73%	77,42%	46,03%	-	-	20,99%	75,68%
If the examination of all requirements provided under Art. 3 of the SPC Regulation was made mandatory	41,38%	40,44%	32,93%	17,65%	58,06%	52,38%	-	-	25,93%	56,76%
If oppositions against SPCs were made possible in cases where the right was granted in violation of Art. 3 of the SPC Regulation	40.69%	40.44%	37.80%	15.69%	74.19%	44.44%			27.16%	67.57%
I do not expect any of the above to have a positive impact	4,14%	4,41%	2,44%	1,96%	3,23%	6,35%	-	-	6,17%	2,70%
Sum of answers	215,17%	214,71%	201,22%	141,18%	300,00%	233,33%	-	-	167,90%	291,89%
No response	2,07%	2,21%	2,44%	3,92%	-	1,59%	-	-	2,47%	-

Question 59
Which of the following measures would you expect to have a positive impact? Please mark all applicable measures. (Multiple responses possible)

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Type of law firm		law firm		npany, Associat esearch institution		С	ompanies by siz	ze	Position at	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
If the procedures for granting SPCs were harmonised within the EU	87,59%	80,95%	85,37%	87,72%	82,93%	83,33%	66,67%	100,00%	90,38%	82,35%	93,88%	89,55%	90,91%
If third parties had the right to file observations like in proceedings before the EPO under Art. 115 EPC	41,38%	38,10%	48,78%	47,37%	46,34%	83,33%	55,56%	52,63%	28,85%	23,53%	42,86%	34,33%	54,55%
If the examination of all requirements provided under Art. 3 of the SPC Regulation was made mandatory	41,38%	52,38%	51,22%	42,11%	41,46%	66,67%	66,67%	36,84%	25,00%	17,65%	40,82%	29,85%	45,45%
If oppositions against SPCs were made possible in cases where the right was granted in violation of Art. 3 of the SPC	10.000	10.000	10.000	45.0404	40 7004	<b>50.00</b> 0			00.0504	07.000		0.1.000/	- 4 4
Regulation I do not expect any of the above	40,69%	42,86%	43,90%	45,61%	48,78%	50,00%	44,44%	57,89%	28,85%	35,29%	44,90%	34,33%	54,55%
to have a positive impact	4,14%	4,76%	7,32%	3,51%	4,88%	16,67%	11,11%	-	1,92%	5,88%	-	2,99%	-
Sum of answers	215,17%	219,05%	236,59%	226,32%	224,39%	300,00%	244,44%	247,37%	175,00%	164,71%	222,45%	191,04%	245,45%
No response	2,07%	-	2,44%	1,75%	2,44%	-	-	-	3,85%	5,88%	-	2,99%	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 59
Which of the following measures would you expect to have a positive impact? Please mark all applicable measures. (Multiple responses possible)

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attit current SF	
		positiv	negativ
Base	145	91	53
If the procedures for granting SPCs were harmonised within the EU	87,59%	86,81%	88,68%
If third parties had the right to file observations like in proceedings before the EPO under Art. 115 EPC	41,38%	27,47%	66,04%
If the examination of all requirements provided under Art. 3 of the SPC Regulation was made mandatory	41,38%	29,67%	62,26%
If oppositions against SPCs were made possible in cases where the right was granted in violation of Art. 3 of the SPC Regulation	40,69%	29,67%	60,38%
I do not expect any of the above to have a positive impact	4,14%	4,40%	3,77%
Sum of answers	215,17%	178,02%	281,13%
No response	2,07%	3,30%	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

There are suggestions for new rules in both SPC Regulations (Regulation 469/2009/EC and Regulation 1610/96/EC) analogous to some EPC rules. Which of the following rules would you welcome under SPC Regulations?

First, would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
			Total	Originator	Generic			institution	companies	companies	
Base	145	136	82	51	31	63	-	-	81	37	
Yes	35,86%	34,56%	17,07%	21,57%	9,68%	60,32%	-	-	37,04%	10,81%	
No	48,28%	49,26%	64,63%	66,67%	61,29%	26,98%	-	-	50,62%	64,86%	
No opinion	13,10%	13,24%	17,07%	9,80%	29,03%	7,94%	-	-	8,64%	24,32%	
No response	2,76%	2,94%	1,22%	1,96%	-	4,76%	-	-	3,70%	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

		Type of law firm		Company, Association, University/research institution is located			C	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Yes	35,86%	57,14%	63,41%	17,54%	19,51%	-	33,33%	26,32%	9,62%	11,76%	20,41%	14,93%	18,18%
No	48,28%	33,33%	21,95%	59,65%	56,10%	100,00%	44,44%	31,58%	80,77%	76,47%	61,22%	68,66%	45,45%
No opinion	13,10%	9,52%	7,32%	21,05%	21,95%	-	22,22%	42,11%	7,69%	11,76%	18,37%	14,93%	36,36%
No response	2,76%	-	7,32%	1,75%	2,44%	-	-	-	1,92%	-	-	1,49%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 60
There are suggestions for new rules in both SPC Regulations (Regulation 469/2009/EC and Regulation 1610/96/EC) analogous to some EPC rules. Which of the following rules would you welcome under SPC Regulations?
First, would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attit current SF	
		positiv	negativ
Base	145	91	53
Yes	35,86%	34,07%	39,62%
No	48,28%	50,55%	45,28%
No opinion	13,10%	10,99%	15,09%
No response	2,76%	4,40%	-
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Secondly, would you welcome a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138 (3) EPC?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	145	136	82	51	31	63	-	-	81	37	
Yes	38,62%	36,76%	17,07%	21,57%	9,68%	66,67%	-	-	38,27%	18,92%	
No	46,21%	48,53%	64,63%	64,71%	64,52%	22,22%	-	-	49,38%	59,46%	
No opinion	13,10%	12,50%	17,07%	11,76%	25,81%	7,94%	-	-	9,88%	21,62%	
No response	2,07%	2,21%	1,22%	1,96%	-	3,17%	-	-	2,47%	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

		Type of law firm			Company, Association, University/research institution is located			ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Yes	38,62%	66,67%	65,85%	17,54%	21,95%	-	11,11%	31,58%	13,46%	5,88%	24,49%	17,91%	18,18%
No	46,21%	23,81%	21,95%	57,89%	51,22%	83,33%	44,44%	31,58%	80,77%	70,59%	59,18%	70,15%	36,36%
No opinion	13,10%	9,52%	7,32%	22,81%	24,39%	16,67%	44,44%	36,84%	3,85%	23,53%	16,33%	10,45%	45,45%
No response	2,07%	-	4,88%	1,75%	2,44%	-	-	-	1,92%	-	-	1,49%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 61

Secondly, would you welcome a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138 (3) EPC?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	91	53			
Yes	38,62%	35,16%	45,28%			
No	46,21%	49,45%	41,51%			
No opinion	13,10%	12,09%	13,21%			
No response	2,07%	3,30%	-			
Total	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 60/61

There are suggestions for new rules in both SPC Regulations (Regulation 469/2009/EC and Regulation 1610/96/EC) analogous to some EPC rules. Which of the following rules would you welcome under SPC Regulations?

First, would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC? Secondly, would you welcome a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138 (3) EPC?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total			Type of st	akeholder			Represer	Representatives of	
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Total Originator G				institution	companies	companies	
Base	145	136	82	51	31	63	-	-	81	37	
Yes in Q60 and in Q61	31,72%	30,88%	12,20%	17,65%	3,23%	57,14%	-	-	33,33%	5,41%	
Yes in Q60 or in Q61	11,03%	9,56%	9,76%	7,84%	12,90%	12,70%	-	-	8,64%	18,92%	
No in Q60 and in Q61	40,00%	41,91%	57,32%	62,75%	48,39%	17,46%	-	-	45,68%	45,95%	
No opinion in Q60 and in Q61	8,28%	8,82%	10,98%	7,84%	16,13%	4,76%	-	-	6,17%	13,51%	
other combinations	6,90%	6,62%	8,54%	1,96%	19,35%	4,76%	-	-	3,70%	16,22%	
No response	2,07%	2,21%	1,22%	1,96%	-	3,17%	-	-	2,47%	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

		Type of	law firm	Company, Association, University/research institution is located			С	ompanies by siz	ze .	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Yes in Q60 and in Q61	31,72%	52,38%	60,98%	12,28%	14,63%	-	11,11%	21,05%	9,62%	5,88%	16,33%	11,94%	18,18%
Yes in Q60 or in Q61	11,03%	19,05%	7,32%	10,53%	12,20%	-	22,22%	15,79%	3,85%	5,88%	12,24%	8,96%	-
No in Q60 and in Q61	40,00%	19,05%	17,07%	49,12%	43,90%	83,33%	22,22%	21,05%	76,92%	64,71%	53,06%	61,19%	36,36%
No opinion in Q60 and in Q61	8,28%	4,76%	4,88%	15,79%	17,07%	-	11,11%	36,84%	1,92%	11,76%	12,24%	7,46%	36,36%
other combinations	6,90%	4,76%	4,88%	10,53%	9,76%	16,67%	33,33%	5,26%	5,77%	11,76%	6,12%	8,96%	9,09%
No response	2,07%	-	4,88%	1,75%	2,44%	-	-	-	1,92%	-	-	1,49%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 60/61

There are suggestions for new rules in both SPC Regulations (Regulation 469/2009/EC and Regulation 1610/96/EC) analogous to some EPC rules. Which of the following rules would you welcome under SPC Regulations?

First, would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC? Secondly, would you welcome a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138 (3) EPC?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	91	53			
Yes in Q60 and in Q61	31,72%	29,67%	35,85%			
Yes in Q60 or in Q61	11,03%	9,89%	13,21%			
No in Q60 and in Q61	40,00%	43,96%	33,96%			
No opinion in Q60 and in Q61	8,28%	7,69%	7,55%			
other combinations	6,90%	5,49%	9,43%			
No response	2,07%	3,30%	-			
Total	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

In your experience as an SPC applicant, are there aspects of the national granting procedures that constitute a burden for applicants, and where harmonisation would make sense?

Base = all companies who already dealt with SPCs (according to Q3 and Q19) or law firm or patent law firm

		Total (without the			Type of st	akeholder			Represer	Representatives of	
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		pants)	Total Originator Generic				institution	companies	companies		
Base	145	136	82	51	31	63	-	-	81	37	
Persons who gave a concrete response (For the results on this question please see report											
section "Verbatims")	56,55%	56,62%	54,88%	76,47%	19,35%	58,73%	-	-	72,84%	21,62%	
Don't know	43,45%	43,38%	45,12%	23,53%	80,65%	41,27%	-	-	27,16%	78,38%	

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	56,55%	52,38%	60,98%	43,86%	41,46%	50,00%	44,44%	15,79%	71,15%	52,94%	48,98%	59,70%	27,27%
Don't know	43,45%	47,62%	39,02%	56,14%	58,54%	50,00%	55,56%	84,21%	28,85%	47,06%	51,02%	40,30%	72,73%

	Total	General attit current SF	
		positiv	negativ
Base	145	91	53
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	56,55%	65,93%	41,51%
Don't know	43,45%	34,07%	58,49%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Does the availability of SPC protection affect your company's decisions about where, in which country, to produce active ingredients?

Base = all companies active in any SPC field (according to Q3)

		Total (without the			Type of st	akeholder			Represer	Representatives of	
	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	3				institution	companies	companies	
Base	82	78	82	51	31	-	-	-	51	31	
Yes	24,39%	24,36%	24,39%	5,88%	54,84%	-	-	-	5,88%	54,84%	
No	18,29%	17,95%	18,29%	29,41%	-	-	-	-	29,41%	-	
Varies from case to case	50,00%	51,28%	50,00%	58,82%	35,48%	-	-	-	58,82%	35,48%	
No opinion	7,32%	6,41%	7,32%	5,88%	9,68%	-	-	-	5,88%	9,68%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%	

		Type of	law firm	Company, Association, University/research institution is located			С	ompanies by siz	ze .	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	82	-	-	57	41	6	9	19	52	17	49	67	11
Yes	24,39%	-	-	29,82%	29,27%	83,33%	11,11%	42,11%	21,15%	17,65%	30,61%	23,88%	36,36%
No	18,29%	-	-	19,30%	19,51%	-	33,33%	15,79%	17,31%	11,76%	18,37%	16,42%	27,27%
Varies from case to case	50,00%	-	-	42,11%	43,90%	-	33,33%	42,11%	55,77%	64,71%	44,90%	55,22%	27,27%
No opinion	7,32%	-	-	8,77%	7,32%	16,67%	22,22%	-	5,77%	5,88%	6,12%	4,48%	9,09%
No response	-	-	-	<u>-</u>	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Ouestion 63

Does the availability of SPC protection affect your company's decisions about where, in which country, to produce active ingredients?

Base = all companies active in any SPC field (according to Q3)

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	82	50	31			
Yes	24,39%	4,00%	58,06%			
No	18,29%	22,00%	9,68%			
Varies from case to case	50,00%	66,00%	25,81%			
No opinion	7,32%	8,00%	6,45%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Is the scope of the Bolar exemption in the case law of a given country a relevant factor for you when deciding where to conduct pre-clinical and clinical trials?

Base = all companies active in any SPC field (according to Q3)

		Total			Type of st	akeholder			Representatives of	
	Total	(without the later accepted partici-		Company		. Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator Generic				institution	companies	companies
Base	82	78	82	51	31	-	-	-	51	31
Yes	57,32%	58,97%	57,32%	54,90%	61,29%	-	-	-	54,90%	61,29%
No	14,63%	15,38%	14,63%	13,73%	16,13%	-	-	-	13,73%	16,13%
Varies from case to case	21,95%	20,51%	21,95%	21,57%	22,58%	-	-	-	21,57%	22,58%
No opinion	4,88%	5,13%	4,88%	7,84%	-	-	-	-	7,84%	-
No response	1,22%	-	1,22%	1,96%	-	-	-	-	1,96%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

		Type of	law firm	Company, Association, University/research institution is located			C	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	82	-	-	57	41	6	9	19	52	17	49	67	11
Yes	57,32%	-	-	54,39%	51,22%	83,33%	11,11%	42,11%	71,15%	82,35%	46,94%	58,21%	63,64%
No	14,63%	-	-	17,54%	17,07%	-	22,22%	26,32%	9,62%	-	18,37%	16,42%	9,09%
Varies from case to case	21,95%	-	-	19,30%	19,51%	16,67%	33,33%	31,58%	15,38%	17,65%	26,53%	22,39%	18,18%
No opinion	4,88%	-	-	7,02%	9,76%	-	22,22%	-	3,85%	-	6,12%	2,99%	-
No response	1,22%	-	-	1,75%	2,44%	-	11,11%	-	-	-	2,04%	-	9,09%
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 64

Is the scope of the Bolar exemption in the case law of a given country a relevant factor for you when deciding where to conduct pre-clinical and clinical trials?

Base = all companies active in any SPC field (according to Q3)

	Total	General attitude towards current SPC system	
		positiv	negativ
Base	82	50	31
Yes	57,32%	58,00%	58,06%
No	14,63%	14,00%	16,13%
Varies from case to case	21,95%	18,00%	25,81%
No opinion	4,88%	8,00%	-
No response	1,22%	2,00%	-
Total	100,00%	100,00%	100,00%

## Ouestion 63/64

Does the availability of SPC protection affect your company's decisions about where, in which country, to produce active ingredients?

Is the scope of the Bolar exemption in the case law of a given country a relevant factor for you when deciding where to conduct pre-clinical and clinical trials?

Base = all companies active in any SPC field (according to Q3)

		Total			Type of st	akeholder			Representatives of		
	Total	(without the later accepted		Company		. Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	82	78	82	51	31	-	-	-	51	31	
Yes in Q63 and in Q64	15,85%	16,67%	15,85%	1,96%	38,71%	-	-	-	1,96%	38,71%	
Yes in Q63 or in Q64	50,00%	50,00%	50,00%	56,86%	38,71%	-	-	-	56,86%	38,71%	
No in Q63 and in Q64	4,88%	5,13%	4,88%	7,84%	-	-	-	-	7,84%	-	
Vaires in in Q63 and in Q64	10,98%	11,54%	10,98%	11,76%	9,68%	-	-	-	11,76%	9,68%	
No opinion in Q63 and in Q64	2,44%	2,56%	2,44%	3,92%	-	-	-	-	3,92%	-	
other combinations	15,85%	14,10%	15,85%	17,65%	12,90%	-	-	-	17,65%	12,90%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%	

	Type of law firm			Con University/re	npany, Associat esearch institution	ion, on is located	С	ompanies by siz	re	Position at	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	82	-	-	57	41	6	9	19	52	17	49	67	11
Yes in Q63 and in Q64	15,85%	-	-	21,05%	19,51%	66,67%	-	31,58%	13,46%	17,65%	16,33%	13,43%	36,36%
Yes in Q63 or in Q64	50,00%	-	-	42,11%	41,46%	33,33%	22,22%	21,05%	65,38%	64,71%	44,90%	55,22%	27,27%
No in Q63 and in Q64	4,88%	-	-	3,51%	-	-	-	5,26%	5,77%	-	6,12%	5,97%	-
Vaires in in Q63 and in Q64	10,98%	-	-	8,77%	7,32%	-	11,11%	21,05%	7,69%	11,76%	10,20%	13,43%	-
No opinion in Q63 and in Q64	2,44%	-	-	3,51%	4,88%	-	11,11%	-	1,92%	-	4,08%	1,49%	-
other combinations	15,85%	-	-	21,05%	26,83%	-	55,56%	21,05%	5,77%	5,88%	18,37%	10,45%	36,36%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 63/64

Does the availability of SPC protection affect your company's decisions about where, in which country, to produce active ingredients?

Is the scope of the Bolar exemption in the case law of a given country a relevant factor for you when deciding where to conduct pre-clinical and clinical trials?

Base = all companies active in any SPC field (according to Q3)

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	82	50	31			
Yes in Q63 and in Q64	15,85%	4,00%	35,48%			
Yes in Q63 or in Q64	50,00%	54,00%	45,16%			
No in Q63 and in Q64	4,88%	6,00%	3,23%			
Vaires in in Q63 and in Q64	10,98%	14,00%	6,45%			
No opinion in Q63 and in Q64	2,44%	4,00%	-			
other combinations	15,85%	18,00%	9,68%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

# Question 65

Are you in favour of a narrow Bolar exemption as laid down in Art. 10(6) Directive 2001/83/EC and Art. 13(6) Directive 2001/82/EC and, by reference, in Art. 27(d) UPCA; or would you favour a broader exemption as recently introduced in UK patent law?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Represer	ntatives of
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Narrow Bolar exemption	18,13%	17,32%	8,54%	13,73%	-	30,16%	19,57%	-	19,19%	2,17%
Broader Bolar exemption	60,62%	60,34%	71,95%	64,71%	83,87%	42,86%	65,22%	50,00%	56,57%	82,61%
No opinion	19,69%	20,67%	19,51%	21,57%	16,13%	23,81%	13,04%	50,00%	22,22%	13,04%
No response	1,55%	1,68%	-	-	-	3,17%	2,17%	-	2,02%	2,17%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

	Type of law firm			Con University/re	npany, Associat search institution	ion, on is located	C	ompanies by siz	e	Position a	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Narrow Bolar exemption	18,13%	23,81%	34,15%	7,02%	9,76%	-	11,11%	15,79%	5,77%	5,88%	10,20%	7,46%	18,18%
Broader Bolar exemption	60,62%	52,38%	36,59%	71,93%	65,85%	100,00%	33,33%	52,63%	84,62%	70,59%	67,35%	74,63%	63,64%
No opinion	19,69%	19,05%	26,83%	21,05%	24,39%	-	55,56%	31,58%	9,62%	23,53%	22,45%	17,91%	18,18%
No response	1,55%	4,76%	2,44%	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 65

Are you in favour of a narrow Bolar exemption as laid down in Art. 10(6) Directive 2001/83/EC and Art. 13(6) Directive 2001/82/EC and, by reference, in Art. 27(d) UPCA; or would you favour a broader exemption as recently introduced in UK patent law?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
Narrow Bolar exemption	18,13%	19,35%	16,67%			
Broader Bolar exemption	60,62%	56,45%	68,18%			
No opinion	19,69%	22,58%	13,64%			
No response	1,55%	1,61%	1,52%			
Total	100,00%	100,00%	100,00%			

# Question 65

Are you in favour of a narrow Bolar exemption as laid down in Art. 10(6) Directive 2001/83/EC and Art. 13(6) Directive 2001/82/EC and, by reference, in Art. 27(d) UPCA; or would you favour a broader exemption as recently introduced in UK patent law?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

			Quest	ion 64	
	Total	Yes	No	Varies from case to case	No opinion
Base	193	47	12	18	4
Narrow Bolar exemption	18,13%	2,13%	8,33%	16,67%	25,00%
Broader Bolar exemption	60,62%	89,36%	75,00%	44,44%	-
No opinion	19,69%	8,51%	16,67%	38,89%	75,00%
No response	1,55%	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 66

SPC protection is not provided in all WTO Member States. Moreover, countries with a significant generic industry exclude new uses of known compounds from patent protection and strongly limit the patentability of new forms of existing active ingredients.

Consequently, the production of a substance for a specific technical or therapeutic purpose in these countries is

or becomes patent-free, while a patent or an SPC in Europe may still exist.

In such an asymmetric situation, to what extent would you expect generic manufacturers to outsource the production of active ingredients that are still protected in Europe, but that are patent-free in several non-European jurisdictions?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Representatives of	
	Total	\ lator		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic	2417	7.00001001011	institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Always	8,29%	7,82%	10,98%	3,92%	22,58%	6,35%	6,52%	-	3,03%	23,91%
In most cases	38,86%	39,66%	37,80%	21,57%	64,52%	50,79%	21,74%	100,00%	24,24%	56,52%
Occasionally	11,92%	12,29%	7,32%	5,88%	9,68%	14,29%	17,39%	-	12,12%	8,70%
Never	2,07%	1,68%	1,22%	1,96%	-	1,59%	4,35%	-	2,02%	-
No opinion, impossible to say	29,02%	27,93%	24,39%	37,25%	3,23%	25,40%	43,48%	-	39,39%	10,87%
No response	9,84%	10,61%	18,29%	29,41%	-	1,59%	6,52%	-	19,19%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Always, In most cases	47,15%	47,49%	48,78%	25,49%	87,10%	57,14%	28,26%	100,00%	27,27%	80,43%
Occasionally, Never	13,99%	13,97%	8,54%	7,84%	9,68%	15,87%	21,74%	-	14,14%	8,70%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 66

SPC protection is not provided in all WTO Member States. Moreover, countries with a significant generic industry exclude new uses of known compounds from patent protection and strongly limit the patentability of new forms of existing active ingredients.

Consequently, the production of a substance for a specific technical or therapeutic purpose in these countries is

or becomes patent-free, while a patent or an SPC in Europe may still exist.

In such an asymmetric situation, to what extent would you expect generic manufacturers to outsource the production of active ingredients that are still protected in Europe, but that are patent-free in several non-European jurisdictions?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of	law firm		npany, Associa esearch institution		C	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Always	8,29%	4,76%	4,88%	12,28%	9,76%	33,33%	11,11%	15,79%	9,62%	5,88%	10,20%	11,94%	9,09%
In most cases	38,86%	38,10%	58,54%	49,12%	51,22%	66,67%	55,56%	57,89%	26,92%	47,06%	42,86%	35,82%	45,45%
Occasionally	11,92%	14,29%	14,63%	8,77%	12,20%	-	22,22%	10,53%	3,85%	-	8,16%	7,46%	-
Never	2,07%	-	2,44%	-	-	-	-	-	1,92%	-	-	1,49%	-
No opinion, impossible to say	29,02%	42,86%	17,07%	15,79%	14,63%	-	11,11%	15,79%	28,85%	29,41%	22,45%	22,39%	36,36%
No response	9,84%	-	2,44%	14,04%	12,20%	-	-	-	28,85%	17,65%	16,33%	20,90%	9,09%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Always, In most cases	47,15%	42,86%	63,41%	61,40%	60,98%	100,00%	66,67%	73,68%	36,54%	52,94%	53,06%	47,76%	54,55%
Occasionally, Never	13,99%	14,29%	17,07%	8,77%	12,20%	-	22,22%	10,53%	5,77%	-	8,16%	8,96%	-

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 66

SPC protection is not provided in all WTO Member States. Moreover, countries with a significant generic industry exclude new uses of known compounds from patent protection and strongly limit the patentability of new forms of existing active ingredients.

Consequently, the production of a substance for a specific technical or therapeutic purpose in these countries is

or becomes patent-free, while a patent or an SPC in Europe may still exist.

In such an asymmetric situation, to what extent would you expect generic manufacturers to outsource the production of active ingredients that are still protected in Europe, but that are patent-free in several non-European jurisdictions?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
Always	8,29%	4,84%	15,15%			
In most cases	38,86%	26,61%	62,12%			
Occasionally	11,92%	14,52%	7,58%			
Never	2,07%	2,42%	1,52%			
No opinion, impossible to say	29,02%	36,29%	13,64%			
No response	9,84%	15,32%	-			
Total	100,00%	100,00%	100,00%			
Always, In most cases	47,15%	31,45%	77,27%			
Occasionally, Never	13,99%	16,94%	9,09%			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 67

The introduction of a "SPC manufacturing waiver" for the export of SPC-protected active ingredients to patent-free markets is currently being considered. This would allow generic companies to manufacture SPC-protected drugs in Europe for export to patent-free countries without infringing the SPC rights. By manufacturing we understand "manufacturing of a final product", and not packaging. What do you think of the idea of introducing such an "SPC waiver"?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Representatives of		
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		pants)	Total	Total Originator Generic				institution	companies	companies	
Base	193	179	82	51	31	63	46	2	99	46	
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")  No opinion	82,90% 17,10%	83,24% 16,76%	85,37% 14,63%	84,31% 15,69%	87,10% 12,90%	76,19% 23,81%	86,96% 13,04%	100,00%	82,83% 17,17%	91,30% 8,70%	

		Type of law firm		Con University/re	npany, Associat esearch institution	tion, on is located	С	ompanies by siz	ze	Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	82,90%	76,19%	78,05%	82,46%	78,05%	100,00%	55,56%	73,68%	94,23%	88,24%	81,63%	91,04%	63,64%
No opinion	17,10%	23,81%	21,95%	17,54%	21,95%	-	44,44%	26,32%	5,77%	11,76%	18,37%	8,96%	36,36%

	Total	General attit current SF	
		positiv	negativ
Base	193	124	66
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	82,90%	82,26%	84,85%
No opinion	17,10%	17,74%	15,15%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 68

Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force?

Please mark the applicable measures:

(Multiple responses possible)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total (without the			Type of st	akeholder			Represen	tatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Granting the patent holder a right to information, enforceable before the courts	55,44%	55,87%	48,78%	72,55%	9,68%	60,32%	63,04%	-	76,77%	17,39%
Making it mandatory for the manufacturer to provide specific labelling for the product	55,44%	56,42%	51,22%	70,59%	19,35%	60,32%	58,70%	-	71,72%	21,74%
Making it mandatory for the manufacturer to communicate to the right holder the quantity produced and the destination before starting distribution	49,74%	50,84%	48,78%	74,51%	6,45%	49,21%	52,17%	50,00%	71,72%	6,52%
New rules shifting the burden of proof for infringement from the SPC holder to the manufacturer	50,78%	51,96%	48,78%	74,51%	6,45%	49,21%	56,52%	50,00%	69,70%	8,70%
Other (please specify);	22,80%	22,91%	26,83%	43,14%	-	9,52%	34,78%	-	35,35%	2,17%
I do not suggest any such measures	19,69%	19,55%	26,83%	3,92%	64,52%	11,11%	19,57%	-	4,04%	60,87%
No opinion	8,81%	8,38%	7,32%	9,80%	3,23%	9,52%	8,70%	50,00%	9,09%	4,35%
Sum of answers	262,69%	265,92%	258,54%	349,02%	109,68%	249,21%	293,48%	150,00%	338,38%	121,74%
No response	1,04%	0,56%	1,22%	-	3,23%	1,59%	-	-	1,01%	2,17%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 68

Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force?

Please mark the applicable measures:

(Multiple responses possible)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Type of	law firm	Con University/re	npany, Associa esearch institution	tion, on is located	Co	ompanies by siz	e	Position at	company	Scope of activ	company vities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Granting the patent holder a right to information, enforceable before the courts	55,44%	61,90%	60,98%	36,84%	36,59%	16,67%	-	31,58%	63,46%	47,06%	44,90%	52,24%	36,36%
Making it mandatory for the manufacturer to provide specific labelling for the product	55,44%	57,14%	60,98%	42,11%	39,02%	16,67%	-	36,84%	65,38%	52,94%	48,98%	53,73%	45,45%
Making it mandatory for the manufacturer to communicate to the right holder the quantity produced and the destination before starting distribution	49,74%	52,38%	48,78%	38,60%	36,59%	-	11,11%	31,58%	61,54%	52,94%	44,90%	53,73%	27,27%
New rules shifting the burden of proof for infringement from the SPC holder to the manufacturer	50,78%	38,10%	56,10%	35,09%	36,59%	-	11,11%	26,32%	63,46%	47,06%	44,90%	52,24%	27,27%
Other (please specify);	22,80%	19,05%	4,88%	17,54%	17,07%	-	-	-	42,31%	23,53%	24,49%	32,84%	-
I do not suggest any such measures	19,69%	9,52%	12,20%	35,09%	36,59%	50,00%	55,56%	36,84%	19,23%	35,29%	24,49%	29,85%	18,18%
No opinion	8,81%	4,76%	12,20%	8,77%	9,76%	16,67%	22,22%	10,53%	3,85%	5,88%	8,16%	2,99%	27,27%
Sum of answers	262,69%	242,86%	256,10%	214,04%	212,20%	100,00%	100,00%	173,68%	319,23%	264,71%	240,82%	277,61%	181,82%
No response	1,04%	-	2,44%	-	-	-	-	-	-	-	2,04%	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 68

Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force?

Please mark the applicable measures:

(Multiple responses possible)

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attit current SF	
		positiv	negativ
Base	193	124	66
Granting the patent holder a right to information, enforceable before the courts	55,44%	69,35%	31,82%
Making it mandatory for the manufacturer to provide specific labelling for the product	55,44%	66,94%	34,85%
Making it mandatory for the manufacturer to communicate to the right holder the quantity produced and the destination before starting distribution	49,74%	62,90%	25,76%
New rules shifting the burden of proof for infringement from the SPC holder to the manufacturer	50,78%	62,10%	30,30%
Other (please specify);	22,80%	33,06%	4,55%
I do not suggest any such measures	19,69%	9,68%	39,39%
No opinion	8,81%	8,87%	6,06%
Sum of answers	262,69%	312,90%	172,73%
No response	1,04%	0,81%	1,52%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 69
The creation of a "unitary SPC" which can be obtained with a single granting procedure is currently under consideration. In your opinion, is there actually a need for creating a "unitary SPC" or is there no actual need?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

		Total			Type of st	akeholder			Representatives of	
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	193	179	82	51	31	63	46	2	99	46
Yes, there is actually a need	75,13%	75,42%	80,49%	90,20%	64,52%	65,08%	80,43%	50,00%	80,81%	67,39%
No, there is no need for that	13,99%	13,41%	12,20%	5,88%	22,58%	22,22%	6,52%	-	13,13%	19,57%
No opinion	10,88%	11,17%	7,32%	3,92%	12,90%	12,70%	13,04%	50,00%	6,06%	13,04%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of law firm		Con University/re	npany, Associat search institution	ion, on is located	C	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	193	21	41	57	41	6	9	19	52	17	49	67	11
Yes, there is actually a need	75,13%	61,90%	65,85%	80,70%	82,93%	50,00%	66,67%	84,21%	82,69%	52,94%	83,67%	79,10%	90,91%
No, there is no need for that	13,99%	38,10%	14,63%	14,04%	9,76%	50,00%	33,33%	5,26%	9,62%	23,53%	12,24%	11,94%	9,09%
No opinion	10,88%	-	19,51%	5,26%	7,32%	-	-	10,53%	7,69%	23,53%	4,08%	8,96%	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 69
The creation of a "unitary SPC" which can be obtained with a single granting procedure is currently under consideration. In your opinion, is there actually a need for creating a "unitary SPC" or is there no actual need?

Base = all companies, universities/research institutions active in any SPC field (according to Q3 and Q17) or law firm or patent law firm or association

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	193	124	66			
Yes, there is actually a need	75,13%	77,42%	71,21%			
No, there is no need for that	13,99%	12,10%	18,18%			
No opinion	10,88%	10,48%	10,61%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU **Question 70** 

And in your opinion, which authority shown on this list should grant a "unitary SPC"?

Base = all respondents who answered "yes" in Q69

		Total (without the			Type of st	akeholder			Represer	tatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	145	135	66	46	20	41	37	1	80	31
National patent offices based on a mutual recognition system	5,52%	5,93%	1,52%	<u>-</u>	5,00%	7,32%	10,81%	-	2,50%	16,13%
An EU authority such as the EU Intellectual Property Office (EUIPO)	8,28%	8,89%	9,09%	4,35%	20,00%	7,32%	5,41%	100,00%	3,75%	12,90%
An EU authority such as the European Medicines Agency (EMA)	6,90%	5,93%	6,06%	-	20,00%	4,88%	10,81%	-	1,25%	22,58%
The EPO	25,52%	25,19%	22,73%	21,74%	25,00%	36,59%	18,92%	-	21,25%	25,81%
A virtual patent office created based on new EU rules and composed of examiners from national patent offices	53,79%	54,07%	60,61%	73,91%	30,00%	43,90%	54,05%	-	71,25%	22,58%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

And in your opinion, which authority shown on this list should grant a "unitary SPC"?

Base = all respondents who answered "yes" in Q69

		Type of law firm		Company, Association, University/research institution is located			C	ompanies by siz	re	Position at	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	13	27	46	34	3	6	16	43	9	41	53	10
National patent offices based on a mutual recognition system	5,52%	-	11,11%	2,17%	2,94%	-	-	6,25%	-	11,11%	-	1,89%	-
An EU authority such as the EU Intellectual Property Office (EUIPO)	8,28%	7,69%	7,41%	10,87%	14,71%	33,33%	16,67%	18,75%	4,65%	-	9,76%	9,43%	10,00%
An EU authority such as the European Medicines Agency (EMA)	6,90%	7,69%	3,70%	8,70%	11,76%	-	-	12,50%	4,65%	11,11%	7,32%	7,55%	-
The EPO	25,52%	30,77%	37,04%	26,09%	29,41%	-	66,67%	31,25%	11,63%	-	24,39%	16,98%	40,00%
A virtual patent office created based on new EU rules and composed of examiners from national patent offices	53,79%	53,85%	40,74%	52,17%	41,18%	66,67%	16,67%	31,25%	79,07%	77,78%	58,54%	64,15%	50,00%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 70 And in your opinion, which authority shown on this list should grant a "unitary SPC"?

Base = all respondents who answered "yes" in Q69

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	96	47			
National patent offices based on a mutual recognition system	5,52%	3,13%	10,64%			
An EU authority such as the EU Intellectual Property Office (EUIPO)	8,28%	5,21%	14,89%			
An EU authority such as the European Medicines Agency (EMA)	6,90%	4,17%	12,77%			
The EPO	25,52%	19,79%	36,17%			
A virtual patent office created based on new EU rules and composed of examiners from national patent offices	53,79%	67,71%	25,53%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Question 71
You opted for a mutual recognition system. In that case, in which language should the "unitary SPC" be filed and prosecuted?

Base = all respondents who answered "yes" in Q69 and "mutual recognition system" in Q70

		Total (without the			Type of st	akeholder			Represer	ntatives of	
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	8	8	1	1 -		3	4	-	2	5	
In English	12,50%	12,50%	-	-	-	33,33%	-	-	50,00%	-	
In the language of the respective national office	87,50%	87,50%	100,00%	-	100,00%	66,67%	100,00%	-	50,00%	100,00%	
No preference	-	-	-	-	-	-	-	-	-	-	
Don't know, no opinion	-	-	-	-	-	-	-	-	-	-	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	-	100,00%	100,00%	100,00%	-	100,00%	100,00%	

		Type of	law firm	Con University/re	npany, Associa esearch institution	tion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of activ	company vities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	8	-	3	1	1	-	-	1	-	1	-	1	-
In English	12,50%	-	33,33%	-	-	-	-	-	-	-	-	-	-
In the language of the respective national office	87,50%	-	66,67%	100,00%	100,00%	-	-	100,00%	-	100,00%	-	100,00%	-
No preference	-	-	-	-	-	-	-	-	-	-	-	-	-
Don't know, no opinion	-	-	-	-	-	-	-	-	-	-	-	-	-
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	100,00%	100,00%	100,00%	-	-	100,00%	-	100,00%	-	100,00%	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 71
You opted for a mutual recognition system. In that case, in which language should the "unitary SPC" be filed and prosecuted?

Base = all respondents who answered "yes" in Q69 and "mutual recognition system" in Q70

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	8	3	5			
In English	12,50%	33,33%	-			
In the language of the respective national office	87,50%	66,67%	100,00%			
No preference	-	-	-			
Don't know, no opinion	-	-	-			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 72
You opted for an EU authority/the EPO/a virtual EU patent office. In that case, in which language should the "unitary SPC" be prosecuted?

Base = all respondents who answered "yes" in Q69 and "EUIPO, EMA, EPO, virtual EU office" in Q70

		Total (without the			Type of st	akeholder			Representatives of	
	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	137	127	65	46	19	38	33	1	78	26
In English only	18,25%	18,90%	18,46%	6,52%	47,37%	18,42%	18,18%	-	10,26%	42,31%
EPO solution (English, French, and German)	66,42%	65,35%	69,23%	86,96%	26,32%	60,53%	66,67%	100,00%	78,21%	30,77%
In the same five working languages of the EUIPO	4,38%	4,72%	3,08%	-	10,53%	5,26%	6,06%	-	1,28%	11,54%
In the official language of any participating Member State, accompanied by a translation										
into English	8,03%	7,87%	6,15%	4,35%	10,53%	10,53%	9,09%	-	6,41%	11,54%
Don't know, no opinion	2,92%	3,15%	3,08%	2,17%	5,26%	5,26%	-	-	3,85%	3,85%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of	law firm	Con University/re	npany, Associat esearch institution	ion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of activ	company vities
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	137	13	24	45	33	3	6	15	43	8	41	52	10
In English only	18,25%	15,38%	20,83%	26,67%	24,24%	33,33%	33,33%	33,33%	11,63%	12,50%	21,95%	21,15%	10,00%
EPO solution (English, French, and German)	66,42%	69,23%	54,17%	57,78%	60,61%	33,33%	66,67%	40,00%	79,07%	62,50%	68,29%	65,38%	80,00%
In the same five working languages of the EUIPO	4,38%	7,69%	4,17%	4,44%	6,06%	33,33%	-	-	4,65%	12,50%	-	3,85%	-
In the official language of any participating Member State, accompanied by a translation into English	8,03%	-	16,67%	8,89%	9,09%	-	-	20,00%	2,33%	-	9,76%	7,69%	-
Don't know, no opinion	2,92%	7,69%	4,17%	2,22%	-	-	-	6,67%	2,33%	12,50%	-	1,92%	10,00%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 72
You opted for an EU authority/the EPO/a virtual EU patent office. In that case, in which language should the "unitary SPC" be prosecuted?

Base = all respondents who answered "yes" in Q69 and "EUIPO, EMA, EPO, virtual EU office" in Q70

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	137	93	42			
In English only	18,25%	12,90%	28,57%			
EPO solution (English, French, and German)	66,42%	74,19%	50,00%			
In the same five working languages of the EUIPO	4,38%	2,15%	9,52%			
In the official language of any participating Member State, accompanied by a translation into English	8,03%	7,53%	9,52%			
Don't know, no opinion	2,92%	3,23%	2,38%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

# Question 73 In which language should the "unitary SPC" be granted and, possibly, translated?

Base = all respondents who answered "yes" in Q69

		Total (without the			Type of st	akeholder			Represer	tatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	145	135	66	46	20	41	37	1	80	31
If a national office is the granting authority, in the language of the granting office plus English	21,38%	22,22%	18,18%	13,04%	30,00%	24,39%	24,32%	-	17,50%	35,48%
In all languages of the countries for which the "unitary SPC" is valid	11,03%	11,11%	9,09%	2,17%	25,00%	19,51%	5,41%	-	6,25%	22,58%
Two-language solution, as with the EUIPO	4,83%	4,44%	4,55%	2,17%	10,00%	4,88%	5,41%	-	2,50%	6,45%
Three-language solution, as with the EPO	62,76%	62,22%	68,18%	82,61%	35,00%	51,22%	64,86%	100,00%	73,75%	35,48%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of	law firm	Con University/re	npany, Associat esearch institution	tion, on is located	C	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	13	27	46	34	3	6	16	43	9	41	53	10
If a national office is the granting authority, in the language of the granting office plus English	21,38%	30,77%	18,52%	26,09%	26,47%	-	33,33%	31,25%	11,63%	11,11%	24,39%	20,75%	10,00%
In all languages of the countries for which the "unitary SPC" is valid	11,03%	-	29,63%	13,04%	11,76%	66,67%	33,33%	6,25%	6,98%	22,22%	2,44%	7,55%	20,00%
Two-language solution, as with the EUIPO	4,83%	7,69%	3,70%	4,35%	5,88%	-	-	12,50%	2,33%	-	7,32%	5,66%	-
Three-language solution, as with the EPO	62,76%	61,54%	48,15%	56,52%	55,88%	33,33%	33,33%	50,00%	79,07%	66,67%	65,85%	66,04%	70,00%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question 73 In which language should the "unitary SPC" be granted and, possibly, translated?

Base = all respondents who answered "yes" in Q69

	Total	General attitude towards current SPC system					
		positiv	negativ				
Base	145	96	47				
If a national office is the granting authority, in the language of the granting office plus English	21,38%	17,71%	29,79%				
In all languages of the countries for which the "unitary SPC" is valid	11,03%	4,17%	23,40%				
Two-language solution, as with the EUIPO	4,83%	5,21%	4,26%				
Three-language solution, as with the EPO	62,76%	72,92%	42,55%				
No response	-	-	-				
Total	100,00%	100,00%	100,00%				

## Ouestion 74

In your view, should the decisions of the body that grants a "unitary SPC" be subject to appeal before the Unified Patent Court (UPC) or before an EU court, such as the Court of First Instance, as in the case with EU trade marks or designs?

Base = all respondents who answered "yes" in Q69

		Total			Type of st	akeholder			Representatives of	
	Total	(without the later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	145	135	66	46	20	41	37	1	80	31
Before the UPC	78,62%	79,26%	81,82%	84,78%	75,00%	85,37%	67,57%	-	85,00%	70,97%
Before an EU court	7,59%	8,15%	4,55%	2,17%	10,00%	9,76%	8,11%	100,00%	2,50%	12,90%
No preference	8,97%	9,63%	9,09%	6,52%	15,00%	-	18,92%	-	6,25%	12,90%
No opinion	4,14%	2,22%	4,55%	6,52%	-	2,44%	5,41%	-	5,00%	3,23%
No response	0,69%	0,74%	-	-	-	2,44%	-	-	1,25%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

		Type of	law firm	Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	13	27	46	34	3	6	16	43	9	41	53	10
Before the UPC	78,62%	92,31%	81,48%	76,09%	76,47%	100,00%	50,00%	68,75%	90,70%	77,78%	82,93%	83,02%	70,00%
Before an EU court	7,59%	7,69%	11,11%	6,52%	5,88%	-	16,67%	6,25%	2,33%	11,11%	2,44%	3,77%	10,00%
No preference	8,97%	-	-	13,04%	14,71%	-	16,67%	18,75%	4,65%	-	9,76%	11,32%	-
No opinion	4,14%	-	3,70%	4,35%	2,94%	-	16,67%	6,25%	2,33%	11,11%	4,88%	1,89%	20,00%
No response	0,69%	-	3,70%	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion 74

In your view, should the decisions of the body that grants a "unitary SPC" be subject to appeal before the Unified Patent Court (UPC) or before an EU court, such as the Court of First Instance, as in the case with EU trade marks or designs?

Base = all respondents who answered "yes" in Q69

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	96	47			
Before the UPC	78,62%	81,25%	72,34%			
Before an EU court	7,59%	5,21%	12,77%			
No preference	8,97%	9,38%	8,51%			
No opinion	4,14%	3,13%	6,38%			
No response	0,69%	1,04%	-			
Total	100,00%	100,00%	100,00%			

Question 75
Should a "unitary SPC" be granted only when the product is covered by a European marketing authorisation granted by EMA?

Base = all respondents who answered "yes" in Q69

		Total (without the			Type of st	akeholder			Represer	entatives of	
	Total later accepted partici-			Company		Law firm	Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	145	135	66	46	20	41	37	1	80	31	
Yes	31,03%	31,85%	24,24%	13,04%	50,00%	46,34%	27,03%	-	16,25%	54,84%	
No	57,93%	57,78%	65,15%	76,09%	40,00%	43,90%	59,46%	100,00%	70,00%	35,48%	
No opinion	11,03%	10,37%	10,61%	10,87%	10,00%	9,76%	13,51%	-	13,75%	9,68%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	

	Type of law firm			Company, Association, University/research institution is located			С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	13	27	46	34	3	6	16	43	9	41	53	10
Yes	31,03%	38,46%	51,85%	32,61%	32,35%	33,33%	50,00%	37,50%	16,28%	11,11%	24,39%	20,75%	50,00%
No	57,93%	53,85%	37,04%	56,52%	58,82%	33,33%	16,67%	50,00%	76,74%	66,67%	65,85%	73,58%	20,00%
No opinion	11,03%	7,69%	11,11%	10,87%	8,82%	33,33%	33,33%	12,50%	6,98%	22,22%	9,76%	5,66%	30,00%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question 75
Should a "unitary SPC" be granted only when the product is covered by a European marketing authorisation granted by EMA?

Base = all respondents who answered "yes" in Q69

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	96	47			
Yes	31,03%	18,75%	53,19%			
No	57,93%	70,83%	34,04%			
No opinion	11,03%	10,42%	12,77%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

## Ouestion 76

Do you have any further comments, questions or criticism regarding the current SPC regulations or case law or on other aspects regarding SPCs that have not been addressed in this survey and that are important to you?

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total			Type of st	akeholder			Represer	Representatives of	
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic	
	pants)	Total	Originator	Generic			institution	companies	companies		
Base	145	136	82	51	31	63	-	-	81	37	
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%	

	Type of law firm			Company, Association, University/research institution is located			C	ompanies by siz	е	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	91	53			
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question 77
If there is anything else you would like to suggest or tell us in connection with this survey, please feel free to do so now:

Base = all companies active in any SPC field (according to Q3) or law firm or patent law firm

		Total (without the			Type of st	akeholder			Represer	tatives of
	Total	` lator		Company		Law firm	Association	University/ Research	Originator	Generic
				Originator	Generic			institution	companies	companies
Base	145	136	82	51	31	63	-	-	81	37
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	100,00%	100,00%

			Type of law firm		npany, Associa esearch institution	tion, on is located	С	ompanies by siz	ze	Position at	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	145	21	41	57	41	6	9	19	52	17	49	67	11
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	145	91	53			
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

## Base = all respondents

		Total (without the			Type of st	akeholder			Represer	ntatives of
	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	203	189	89	51	31	63	46	5	99	46
Under 30	1,97%	2,12%	1,12%	1,96%	-	1,59%	4,35%	-	3,03%	- -
30 - 39	17,24%	16,93%	19,10%	13,73%	22,58%	11,11%	21,74%	20,00%	14,14%	21,74%
40 - 49	35,96%	35,98%	37,08%	35,29%	45,16%	46,03%	21,74%	20,00%	41,41%	32,61%
50 - 59	32,02%	31,75%	32,58%	31,37%	32,26%	23,81%	39,13%	60,00%	27,27%	34,78%
60 and over	6,40%	6,35%	2,25%	3,92%	-	11,11%	8,70%	-	4,04%	8,70%
No response	6,40%	6,88%	7,87%	13,73%	-	6,35%	4,35%	-	10,10%	2,17%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

	Type of law firm			Con University/re	npany, Associat esearch institutio	ion, on is located	С	ompanies by siz	ze	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	203	21	41	64	48	6	14	20	53	19	53	70	15
Under 30	1,97%	4,76%	-	1,56%	2,08%	-	-	5,00%	-	-	1,89%	1,43%	-
30 - 39	17,24%	23,81%	4,88%	20,31%	25,00%	-	35,71%	20,00%	13,21%	-	30,19%	14,29%	33,33%
40 - 49	35,96%	33,33%	53,66%	39,06%	33,33%	16,67%	28,57%	60,00%	30,19%	36,84%	37,74%	37,14%	40,00%
50 - 59	32,02%	19,05%	24,39%	29,69%	31,25%	83,33%	21,43%	15,00%	43,40%	52,63%	24,53%	35,71%	26,67%
60 and over	6,40%	9,52%	12,20%	1,56%	2,08%	-	7,14%	-	1,89%	5,26%	-	2,86%	-
No response	6,40%	9,52%	4,88%	7,81%	6,25%	-	7,14%	-	11,32%	5,26%	5,66%	8,57%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S1 What is your age? (Please check the applicable category)

Base = all respondents

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	203	124	66			
Under 30	1,97%	3,23%	-			
30 - 39	17,24%	12,10%	24,24%			
40 - 49	35,96%	38,71%	33,33%			
50 - 59	32,02%	28,23%	36,36%			
60 and over	6,40%	8,06%	4,55%			
No response	6,40%	9,68%	1,52%			
Total	100,00%	100,00%	100,00%			

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S2 What position do you hold at your company?

Base = all companies

		Total (without the			Type of st	akeholder			Represer	ntatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
Owner	3,37%	3,53%	3,37%	1,96%	-	-	-	-	1,96%	-
Member of the board of directors	3,37%	3,53%	3,37%	1,96%	6,45%	-	-	-	1,96%	6,45%
Director	14,61%	15,29%	14,61%	17,65%	12,90%	-	-	-	17,65%	12,90%
Executive, managerial position	39,33%	38,82%	39,33%	47,06%	29,03%	-	-	-	47,06%	29,03%
Employee in non-managerial position	20,22%	18,82%	20,22%	9,80%	35,48%	-	-	-	9,80%	35,48%
Other	15,73%	16,47%	15,73%	15,69%	16,13%	-	-	=	15,69%	16,13%
No response	3,37%	3,53%	3,37%	5,88%	-	-	-	-	5,88%	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Owner, Member of the board of directors, Director  Executive, managerial position,	21,35%	22,35%	21,35%	21,57%	19,35%	-	-	-	21,57%	19,35%
Employee in non-managerial position, other	59,55%	57,65%	59,55%	56,86%	64,52%	-	-	-	56,86%	64,52%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S2 What position do you hold at your company?

Base = all companies

	Type of law firm		law firm		npany, Associatesearch institution		С	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Owner	3,37%	-	-	4,69%	6,25%	-	21,43%	-	-	15,79%	-	2,86%	6,67%
Member of the board of directors	3,37%	-	-	3,13%	2,08%	-	7,14%	-	3,77%	15,79%	-	4,29%	-
Director	14,61%	-	-	10,94%	8,33%	33,33%	-	10,00%	20,75%	68,42%	-	14,29%	20,00%
Executive, managerial position	39,33%	-	-	39,06%	43,75%	16,67%	21,43%	50,00%	41,51%	-	66,04%	40,00%	40,00%
Employee in non-managerial position	20,22%	-	-	23,44%	25,00%	16,67%	21,43%	35,00%	13,21%	-	33,96%	20,00%	20,00%
Other	15,73%	-	-	14,06%	10,42%	33,33%	21,43%	5,00%	16,98%	-	-	15,71%	13,33%
No response	3,37%	-	-	4,69%	4,17%	-	7,14%	-	3,77%	-	-	2,86%	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Owner, Member of the board of directors, Director	21,35%	-	-	18,75%	16,67%	33,33%	28,57%	10,00%	24,53%	100,00%	-	21,43%	26,67%
Executive, managerial position, Employee in non-managerial position, other	59,55%	-	-	62,50%	68,75%	33,33%	42,86%	85,00%	54,72%	-	100,00%	60,00%	60,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S2 What position do you hold at your company?

Base = all companies

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	89	50	31			
Owner	3,37%	2,00%	-			
Member of the board of directors	3,37%	6,00%	-			
Director	14,61%	16,00%	16,13%			
Executive, managerial position	39,33%	38,00%	41,94%			
Employee in non-managerial position	20,22%	14,00%	29,03%			
Other	15,73%	18,00%	12,90%			
No response	3,37%	6,00%	-			
Total	100,00%	100,00%	100,00%			
Owner, Member of the board of directors, Director	21,35%	24,00%	16,13%			
Executive, managerial position, Employee in non-managerial position, other	59,55%	52,00%	70,97%			

Base = all law firm or patent law firm

		Total (without the	Type of stakeholder							Representatives of		
	Total	later accepted	Company			Law firm	Association	University/ Research	Originator	Generic		
		partici- pants)	Total	Originator	Generic			institution	companies	companies		
Base	63	58	-	-	-	63	-	-	30	6		
Partner	77,78%	75,86%	-	-	-	77,78%	-	-	83,33%	100,00%		
Employed as lawyer/patent attorney	19,05%	20,69%	-	-	-	19,05%	-	-	13,33%	-		
Other law firm employee	1,59%	1,72%	-	-	-	1,59%	-	-	-	-		
No response	1,59%	1,72%	-	-	-	1,59%	-	-	3,33%	-		
Total	100,00%	100,00%	-	-	-	100,00%	-	-	100,00%	100,00%		

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	63	21	41	-	-	-	-	-	-	-	-	-	-
Partner	77,78%	85,71%	75,61%	-	-	-	-	-	-	-	-	-	-
Employed as lawyer/patent attorney	19,05%	9,52%	21,95%	-	-	-	-	-	-	-	-	-	-
Other law firm employee	1,59%	4,76%	-	-	-	-	-	-	-	-	-	-	-
No response	1,59%	-	2,44%	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	-	-	-	-	-	-	-	-	-	-

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S3 What position do you hold at your office/firm?

Base = all law firm or patent law firm

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	63	41	22			
Partner	77,78%	80,49%	72,73%			
Employed as lawyer/patent attorney	19,05%	14,63%	27,27%			
Other law firm employee	1,59%	2,44%	-			
No response	1,59%	2,44%	-			
Total	100,00%	100,00%	100,00%			

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S4
What is the total number of employees at your company?
If you work for a company with offices, plants or facilities in more than one location, please indicate the total number of all employees.

## Base = all companies

		Total		Type of stakeholder						ntatives of
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
Less than 100	15,73%	15,29%	15,73%	11,76%	9,68%	<u>-</u>	-	-	11,76%	9,68%
100 - 499	15,73%	16,47%	15,73%	11,76%	22,58%	-	-	-	11,76%	22,58%
500 - 999	6,74%	7,06%	6,74%	1,96%	16,13%	-	-	-	1,96%	16,13%
1,000 - 9,999	25,84%	25,88%	25,84%	29,41%	25,81%	-	-	-	29,41%	25,81%
10,000 or more	33,71%	34,12%	33,71%	43,14%	22,58%	-	-	-	43,14%	22,58%
No response	2,25%	1,18%	2,25%	1,96%	3,23%	-	-	-	1,96%	3,23%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

		Type of	law firm	Con University/re	npany, Associat esearch institutio	ion, on is located	Companies by size			Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Less than 100	15,73%	-	-	21,88%	25,00%	-	100,00%	-	-	21,05%	11,32%	8,57%	40,00%
100 - 499	15,73%	-	-	20,31%	22,92%	-	-	70,00%	-	5,26%	22,64%	14,29%	26,67%
500 - 999	6,74%	-	-	9,38%	12,50%	-	-	30,00%	-	5,26%	9,43%	7,14%	6,67%
1,000 - 9,999	25,84%	-	-	25,00%	18,75%	66,67%	-	-	43,40%	31,58%	26,42%	27,14%	26,67%
10,000 or more	33,71%	-	-	23,44%	20,83%	33,33%	-	-	56,60%	36,84%	28,30%	42,86%	-
No response	2,25%	-	-	-	-	-	-	-	-	-	1,89%	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S4
What is the total number of employees at your company?
If you work for a company with offices, plants or facilities in more than one location, please indicate the total number of all employees.

## Base = all companies

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	89	50	31
Less than 100	15,73%	14,00%	6,45%
100 - 499	15,73%	12,00%	19,35%
500 - 999	6,74%	4,00%	12,90%
1,000 - 9,999	25,84%	22,00%	38,71%
10,000 or more	33,71%	46,00%	19,35%
No response	2,25%	2,00%	3,23%
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion S5

Approximately how high was the total turnover of your company in the year 2015 in euros? Again, if you work for a company with offices, plants or facilities in more than one location, please indicate the total turnover of all locations on a worldwide basis.

Base = all companies

		Total (without the				Representatives of				
	Total	later accepted		Company		I aw firm	Law firm Association		Originator	Generic
		partici- pants)	Total	Originator	Generic	2417	7.0000.0	Research institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
Less than 10 million euros	12,36%	11,76%	12,36%	9,80%	3,23%	-	-	-	9,80%	3,23%
10 to less than 100 million euros	16,85%	17,65%	16,85%	9,80%	29,03%	-	-	-	9,80%	29,03%
100 to less than 500 million euros	11,24%	11,76%	11,24%	9,80%	16,13%	-	-	-	9,80%	16,13%
500 to less than 1 billion euros	3,37%	3,53%	3,37%	-	9,68%	-	-	-	-	9,68%
1 billion to less than 10 billion euros	23,60%	22,35%	23,60%	31,37%	16,13%	-	-	-	31,37%	16,13%
10 billion euros or more	24,72%	25,88%	24,72%	33,33%	12,90%	-	-	-	33,33%	12,90%
No response	7,87%	7,06%	7,87%	5,88%	12,90%	-	-	-	5,88%	12,90%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

		Type of	law firm		npany, Associat search institution		Companies by size			Position at	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Less than 10 million euros	12,36%	-	-	17,19%	18,75%	-	71,43%	5,00%	-	26,32%	7,55%	5,71%	40,00%
10 to less than 100 million euros	16,85%	-	-	23,44%	27,08%	-	21,43%	50,00%	3,77%	-	22,64%	18,57%	13,33%
100 to less than 500 million euros	11,24%	-	-	14,06%	16,67%	-	-	30,00%	7,55%	15,79%	13,21%	8,57%	26,67%
500 to less than 1 billion euros	3,37%	-	-	4,69%	-	50,00%	-	-	5,66%	5,26%	1,89%	1,43%	13,33%
1 billion to less than 10 billion euros	23,60%	-	-	20,31%	20,83%	33,33%	-	-	39,62%	31,58%	22,64%	30,00%	-
10 billion euros or more	24,72%	-	-	15,63%	10,42%	16,67%	-	-	41,51%	15,79%	22,64%	31,43%	-
No response	7,87%	-	-	4,69%	6,25%	-	7,14%	15,00%	1,89%	5,26%	9,43%	4,29%	6,67%
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Ouestion S5

Approximately how high was the total turnover of your company in the year 2015 in euros? Again, if you work for a company with offices, plants or facilities in more than one location, please indicate the total turnover of all locations on a worldwide basis.

Base = all companies

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	89	50	31
Less than 10 million euros	12,36%	10,00%	3,23%
10 to less than 100 million euros	16,85%	16,00%	16,13%
100 to less than 500 million euros	11,24%	4,00%	25,81%
500 to less than 1 billion euros	3,37%	-	9,68%
1 billion to less than 10 billion euros	23,60%	30,00%	19,35%
10 billion euros or more	24,72%	34,00%	12,90%
No response	7,87%	6,00%	12,90%
Total	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S4/S5
What is the total number of employees at your company?
Approximately how high was the total turnover of your company in the year 2015 in euros?

## Base = all companies

		Total (without the		Type of stakeholder						tatives of
	Total	later accepted partici-		Company		Law firm	Association	University/ on Research	Originator	Generic
		pants)	Total	Originator	Generic			institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
Small companies: less than 100 employees, less than 100 million turnover	15,73%	15,29%	15,73%	11,76%	9,68%	-	-	-	11,76%	9,68%
Medium companies: 100 bis 999 employees, 100 millions up to 1 billion turnover	22,47%	23,53%	22,47%	13,73%	38,71%	-	-	-	13,73%	38,71%
Large companies: 1000 employees and more, 1 billion turnover and more	59,55%	60,00%	59,55%	72,55%	48,39%	-	-	-	72,55%	48,39%
No response	2,25%	1,18%	2,25%	1,96%	3,23%	-	-	-	1,96%	3,23%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

		Type of	law firm	Con University/re	npany, Associat esearch institution	tion, on is located	Companies by size			Position at	company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Small companies: less than 100 employees, less than 100 million turnover	15,73%	-	-	21,88%	25,00%	-	100,00%	-	-	21,05%	11,32%	8,57%	40,00%
Medium companies: 100 bis 999 employees, 100 millions up to 1 billion turnover	22,47%	-	-	29,69%	35,42%	-	-	100,00%	-	10,53%	32,08%	21,43%	33,33%
Large companies: 1000 employees and more, 1 billion turnover and more	59,55%	-	-	48,44%	39,58%	100,00%	-	-	100,00%	68,42%	54,72%	70,00%	26,67%
No response	2,25%	-	-	-	-	-	-	-	-	-	1,89%	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S4/S5
What is the total number of employees at your company?
Approximately how high was the total turnover of your company in the year 2015 in euros?

## Base = all companies

	Total	General attitude towards current SPC system			
		positiv	negativ		
Base	89	50	31		
Small companies: less than 100 employees, less than 100 million turnover	15,73%	14,00%	6,45%		
Medium companies: 100 bis 999 employees, 100 millions up to 1 billion turnover	22,47%	16,00%	32,26%		
Large companies: 1000 employees and more, 1 billion turnover and more	59,55%	68,00%	58,06%		
No response	2,25%	2,00%	3,23%		
Total	100,00%	100,00%	100,00%		

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question S6
In how many EU Member States does your company offer its products or services?

Base = all companies

		Total (without the				Representatives of				
	Total	later accepted	ed Company		Law firm Ass		University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
In 1 EU Member State	4,49%	4,71%	4,49%	1,96%	3,23%	-	-	-	1,96%	3,23%
In 2 - 4 EU Member States	6,74%	5,88%	6,74%	5,88%	3,23%	-	-	-	5,88%	3,23%
In 5 - 9 EU Member States	5,62%	5,88%	5,62%	5,88%	6,45%	-	-	-	5,88%	6,45%
In 10 - 28 EU Member States	78,65%	80,00%	78,65%	80,39%	83,87%	-	-	-	80,39%	83,87%
No response	4,49%	3,53%	4,49%	5,88%	3,23%	-	-	-	5,88%	3,23%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
Low, Medium (in 1 - 9 member states)	16,85%	16,47%	16,85%	13,73%	12,90%	-	-	-	13,73%	12,90%
High (in 10 or more member states)	78,65%	80,00%	78,65%	80,39%	83,87%	-	-	-	80,39%	83,87%

		Type of	law firm	Con University/re	npany, Associa esearch institution	tion, on is located	Companies by size		Position at company		Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
In 1 EU Member State	4,49%	-	-	6,25%	8,33%	-	14,29%	5,00%	1,89%	5,26%	5,66%	-	26,67%
In 2 - 4 EU Member States	6,74%	-	-	9,38%	8,33%	16,67%	28,57%	5,00%	1,89%	5,26%	7,55%	-	40,00%
In 5 - 9 EU Member States	5,62%	-	-	7,81%	6,25%	16,67%	-	15,00%	3,77%	10,53%	3,77%	-	33,33%
In 10 - 28 EU Member States	78,65%	-	-	73,44%	72,92%	66,67%	42,86%	75,00%	92,45%	78,95%	79,25%	100,00%	-
No response	4,49%	-	-	3,13%	4,17%	-	14,29%	-	-	-	3,77%	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
Low, Medium (in 1 - 9 member states)	16,85%	-	-	23,44%	22,92%	33,33%	42,86%	25,00%	7,55%	21,05%	16,98%	-	100,00%
High (in 10 or more member states)	78,65%	-	-	73,44%	72,92%	66,67%	42,86%	75,00%	92,45%	78,95%	79,25%	100,00%	-

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S6 In how many EU Member States does your company offer its products or services?

Base = all companies

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	89	50	31
In 1 EU Member State	4,49%	-	6,45%
In 2 - 4 EU Member States	6,74%	4,00%	6,45%
In 5 - 9 EU Member States	5,62%	4,00%	6,45%
In 10 - 28 EU Member States	78,65%	86,00%	77,42%
No response	4,49%	6,00%	3,23%
Total	100,00%	100,00%	100,00%
Low, Medium (in 1 - 9 member states)	16,85%	8,00%	19,35%
High (in 10 or more member states)	78,65%	86,00%	77,42%

Question S7
For each of the activities listed below, please select the applicable share that your company completes in the EU.

Base = all companies

		Total (without the				Represer	ntatives of			
Research & development	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic	Law IIIII	7133001411011	institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
All/ almost all	30,34%	30,59%	30,34%	35,29%	19,35%	-	-	<u>-</u>	35,29%	19,35%
A fairly large share	43,82%	43,53%	43,82%	43,14%	48,39%	-	-	-	43,14%	48,39%
A fairly small share	14,61%	14,12%	14,61%	13,73%	19,35%	-	-	-	13,73%	19,35%
None/ almost none	7,87%	8,24%	7,87%	3,92%	9,68%	-	-	-	3,92%	9,68%
No response	3,37%	3,53%	3,37%	3,92%	3,23%	-	-	-	3,92%	3,23%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
All/ almost all, A fairly large share	74,16%	74,12%	74,16%	78,43%	67,74%	-	-	-	78,43%	67,74%
A fairly small share, None/ almost none	22,47%	22,35%	22,47%	17,65%	29,03%	-	-	-	17,65%	29,03%

		Type of	law firm		npany, Associa esearch institution		Companies by size			Position a	t company	Scope of company activities	
Research & development	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
All/ almost all	30,34%	-	-	39,06%	37,50%	33,33%	57,14%	50,00%	16,98%	42,11%	26,42%	21,43%	66,67%
A fairly large share	43,82%	-	-	40,63%	41,67%	66,67%	14,29%	30,00%	56,60%	31,58%	47,17%	51,43%	13,33%
A fairly small share	14,61%	-	-	10,94%	10,42%	-	-	15,00%	18,87%	15,79%	18,87%	17,14%	6,67%
None/ almost none	7,87%	-	-	6,25%	8,33%	-	21,43%	5,00%	5,66%	10,53%	7,55%	7,14%	13,33%
No response	3,37%	-	-	3,13%	2,08%	-	7,14%	-	1,89%	-	-	2,86%	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
All/ almost all, A fairly large share	74,16%	-	-	79,69%	79,17%	100,00%	71,43%	80,00%	73,58%	73,68%	73,58%	72,86%	80,00%
A fairly small share, None/ almost none	22,47%	-	-	17,19%	18,75%	-	21,43%	20,00%	24,53%	26,32%	26,42%	24,29%	20,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S7
For each of the activities listed below, please select the applicable share that your company completes in the EU.

Base = all companies

Research & development	Total		ude towards PC system
·		positiv	negativ
Base	89	50	31
All/ almost all	30,34%	30,00%	25,81%
A fairly large share	43,82%	44,00%	48,39%
A fairly small share	14,61%	14,00%	19,35%
None/ almost none	7,87%	6,00%	6,45%
No response	3,37%	6,00%	-
Total	100,00%	100,00%	100,00%
All/ almost all, A fairly large share	74,16%	74,00%	74,19%
A fairly small share, None/ almost none	22,47%	20,00%	25,81%

Question S7
For each of the activities listed below, please select the applicable share that your company completes in the EU.

Base = all companies

		Total (without the				Represer	Representatives of			
Manufacturing	Total	later accepted		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.0	institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
All/ almost all	19,10%	20,00%	19,10%	15,69%	19,35%	-	-	-	15,69%	19,35%
A fairly large share	53,93%	54,12%	53,93%	62,75%	45,16%	-	-	-	62,75%	45,16%
A fairly small share	12,36%	11,76%	12,36%	5,88%	19,35%	-	-	-	5,88%	19,35%
None/ almost none	8,99%	8,24%	8,99%	7,84%	12,90%	-	-	-	7,84%	12,90%
No response	5,62%	5,88%	5,62%	7,84%	3,23%	-	-	-	7,84%	3,23%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
All/ almost all, A fairly large share	73,03%	74,12%	73,03%	78,43%	64,52%	-	-	-	78,43%	64,52%
A fairly small share, None/ almost none	21,35%	20,00%	21,35%	13,73%	32,26%	-	-	-	13,73%	32,26%

		Type of	law firm		Company, Association, University/research institution is located  Companies by size  Position at company			Companies by size		t company	Scope of company activities		
Manufacturing	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
All/ almost all	19,10%	-	-	23,44%	25,00%	16,67%	14,29%	50,00%	9,43%	15,79%	20,75%	17,14%	33,33%
A fairly large share	53,93%	-	-	46,88%	45,83%	66,67%	14,29%	40,00%	69,81%	52,63%	54,72%	57,14%	46,67%
A fairly small share	12,36%	-	-	14,06%	12,50%	16,67%	14,29%	5,00%	15,09%	21,05%	13,21%	12,86%	13,33%
None/ almost none	8,99%	-	-	9,38%	10,42%	-	35,71%	5,00%	3,77%	5,26%	9,43%	8,57%	6,67%
No response	5,62%	-	-	6,25%	6,25%	-	21,43%	-	1,89%	5,26%	1,89%	4,29%	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
All/ almost all, A fairly large share	73,03%	-	-	70,31%	70,83%	83,33%	28,57%	90,00%	79,25%	68,42%	75,47%	74,29%	80,00%
A fairly small share, None/ almost none	21,35%	-	-	23,44%	22,92%	16,67%	50,00%	10,00%	18,87%	26,32%	22,64%	21,43%	20,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S7
For each of the activities listed below, please select the applicable share that your company completes in the EU.

Base = all companies

Manufacturing	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	89	50	31
All/ almost all	19,10%	14,00%	19,35%
A fairly large share	53,93%	60,00%	51,61%
A fairly small share	12,36%	8,00%	16,13%
None/ almost none	8,99%	8,00%	12,90%
No response	5,62%	10,00%	-
Total	100,00%	100,00%	100,00%
All/ almost all, A fairly large share	73,03%	74,00%	70,97%
A fairly small share, None/ almost none	21,35%	16,00%	29,03%

Question S7
For each of the activities listed below, please select the applicable share that your company completes in the EU.

Base = all companies

		Total (without the				Represer	tatives of			
Distribution, marketing	Total	` later accepted		Company				University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic		7.0000.00.00	institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
All/ almost all	19,10%	18,82%	19,10%	17,65%	19,35%	-	-	-	17,65%	19,35%
A fairly large share	61,80%	62,35%	61,80%	60,78%	64,52%	-	-	-	60,78%	64,52%
A fairly small share	10,11%	10,59%	10,11%	9,80%	9,68%	-	-	-	9,80%	9,68%
None/ almost none	3,37%	2,35%	3,37%	3,92%	3,23%	-	-	-	3,92%	3,23%
No response	5,62%	5,88%	5,62%	7,84%	3,23%	-	-	-	7,84%	3,23%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%
All/ almost all, A fairly large share	80,90%	81,18%	80,90%	78,43%	83,87%	-	-	-	78,43%	83,87%
A fairly small share, None/ almost none	13,48%	12,94%	13,48%	13,73%	12,90%	-	-	-	13,73%	12,90%

		Type of	law firm	Con University/re	npany, Associat esearch institution	tion, on is located	Companies by size		Companies by size Position at company		t company	Scope of company activities	
Distribution, marketing	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
All/ almost all	19,10%	-	-	18,75%	20,83%	-	21,43%	35,00%	13,21%	15,79%	18,87%	18,57%	26,67%
A fairly large share	61,80%	-	-	59,38%	56,25%	100,00%	35,71%	45,00%	75,47%	68,42%	62,26%	65,71%	53,33%
A fairly small share	10,11%	-	-	10,94%	10,42%	-	7,14%	15,00%	9,43%	10,53%	11,32%	10,00%	13,33%
None/ almost none	3,37%	-	-	4,69%	6,25%	-	21,43%	-	-	-	3,77%	1,43%	6,67%
No response	5,62%	-	-	6,25%	6,25%	-	14,29%	5,00%	1,89%	5,26%	3,77%	4,29%	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%
All/ almost all, A fairly large share	80,90%	-	-	78,13%	77,08%	100,00%	57,14%	80,00%	88,68%	84,21%	81,13%	84,29%	80,00%
A fairly small share, None/ almost none	13,48%	-	-	15,63%	16,67%	-	28,57%	15,00%	9,43%	10,53%	15,09%	11,43%	20,00%

Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

Question S7
For each of the activities listed below, please select the applicable share that your company completes in the EU.

Base = all companies

Distribution, marketing	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	89	50	31			
All/ almost all	19,10%	18,00%	16,13%			
A fairly large share	61,80%	56,00%	74,19%			
A fairly small share	10,11%	12,00%	6,45%			
None/ almost none	3,37%	4,00%	3,23%			
No response	5,62%	10,00%	-			
Total	100,00%	100,00%	100,00%			
All/ almost all, A fairly large share	80,90%	74,00%	90,32%			
A fairly small share, None/ almost none	13,48%	16,00%	9,68%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Is your company a parent company, a subsidiary or an independent company?

#### Base = all companies

		Total		Type of stakeholder						tatives of
	Total	(without the later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
		partici- pants)	Total	Originator	Generic			institution	companies	companies
Base	89	85	89	51	31	-	-	-	51	31
Parent company	43,82%	44,71%	43,82%	56,86%	29,03%	-	-	-	56,86%	29,03%
Subsidiary	25,84%	23,53%	25,84%	19,61%	32,26%	-	-	-	19,61%	32,26%
Independent	30,34%	31,76%	30,34%	23,53%	38,71%	-	-	-	23,53%	38,71%
No response	-	-	-	-	-	-	-	-	-	-
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%

	Type of law firm		law firm	Company, Association, University/research institution is located			С	ompanies by siz	e	Position a	t company	Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	89	-	-	64	48	6	14	20	53	19	53	70	15
Parent company	43,82%	-	-	40,63%	37,50%	66,67%	14,29%	30,00%	56,60%	21,05%	49,06%	50,00%	20,00%
Subsidiary	25,84%	-	-	20,31%	16,67%	33,33%	35,71%	10,00%	28,30%	36,84%	22,64%	22,86%	33,33%
Independent	30,34%	-	-	39,06%	45,83%	-	50,00%	60,00%	15,09%	42,11%	28,30%	27,14%	46,67%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU **Question S8** 

Is your company a parent company, a subsidiary or an independent company?

Base = all companies

	Total	General attit current SF	ude towards PC system
		positiv	negativ
Base	89	50	31
Parent company	43,82%	48,00%	41,94%
Subsidiary	25,84%	24,00%	25,81%
Independent	30,34%	28,00%	32,26%
No response	-	-	-
Total	100,00%	100,00%	100,00%

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Is your parent company registered outside the European Union?

Base = all companies and "Subsidiary" in S8

		Total (without the				Representatives of					
	Total	Total later accepted		Company			Association	University/ Research	Originator	Generic	
		partici- pants)	Total	Originator	Generic	Law firm		institution	companies	companies	
Base	23	20	23	10	10	-	-	-	10	10	
Yes	65,22%	65,00%	65,22%	70,00%	70,00%	<del>-</del>	-	-	70,00%	70,00%	
No	34,78%	35,00%	34,78%	30,00%	30,00%	-	-	-	30,00%	30,00%	
No response	-	-	-	-	-	-	-	-	-	-	
Total	100,00%	100,00%	100,00%	100,00%	100,00%	-	-	-	100,00%	100,00%	

	Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities		
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	23	-	-	13	8	2	5	2	15	7	12	16	5
Yes	65,22%	-	-	38,46%	37,50%	50,00%	40,00%	50,00%	73,33%	85,71%	58,33%	81,25%	20,00%
No	34,78%	-	-	61,54%	62,50%	50,00%	60,00%	50,00%	26,67%	14,29%	41,67%	18,75%	80,00%
No response	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100,00%	-	-	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU Question S9

Is your parent company registered outside the European Union?

Base = all companies and "Subsidiary" in S8

	Total	General attitude towards current SPC system				
		positiv	negativ			
Base	23	12	8			
Yes	65,22%	75,00%	62,50%			
No	34,78%	25,00%	37,50%			
No response	-	-	-			
Total	100,00%	100,00%	100,00%			

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question S10 What position do you hold at the association you represent? Please specify:

#### Base = all associations

		Total (without the				Representatives of				
	Total	later accepted	later				Association	University/ Research	Originator	Generic
		pants)	Total	Originator	Generic	Law firm		institution	companies	companies
Base	46	41	-	-	-	-	46	-	18	9
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	-	-	-	-	100,00%	-	100,00%	100,00%

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	46	-	-	-	-	-	-	-	-	-	-	-	-
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

	Total	General attitude towards current SPC system			
		positiv	negativ		
Base	46	33	12		
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	100,00%		

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

Question S11 What position do you hold at the university or research institution you represent? Please specify:

#### Base = all university or research institution

		Total (without the				Representatives of				
	Total	later accepted partici-		Company		Law firm	Association	University/ Research	Originator	Generic
	partici- pants)	Total	Originator	Generic			institution	companies	companies	
Base	5	5	-	-	-	-	-	5	-	-
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	100,00%	-	-	-	-	-	100,00%	-	-

		Type of law firm		Company, Association, University/research institution is located			Companies by size			Position at company		Scope of company activities	
	Total	Global	Regional, national, local	EU 28	EZ 19	New Member State since 2004	Small	Medium	Large	Owner, Member of the board, Director	Manage- rial, Non- managerial position	High (in 10 or more Member States)	Low/ medium (in 1-9 Member States)
Base	5	-	-	-	-	-	-	-	-	-	-	-	-
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	-	-	-	-	-	-	-	-	-	-	-	-

	Total	General attitude towards current SPC system			
		positiv	negativ		
Base	5	-	1		
Persons who gave a concrete response (For the results on this question please see report section "Verbatims")	100,00%	-	100,00%		

Source: Allensbach Archives, IfD-Survey 3754, Fieldwork from May 22 - June 23, 2017

# 4.3 Report on the verbatim responses to the openended questions and additional comments

## Q2: In which country is the company entity you represent located?

- Macedonia
- Company HQ is in the UK, but we operate in all EU Member States
- headquartered in the UK but with affiliates operating in all EU member states
- United States, but company has affiliates in all EU member states
- Japan with affiliates operating in all EU member states.
- Japan but with affiliates operating in all EU Member States
- USA but operating in most EU states
- United States but with worldwide affiliates operating in all EU Member States.
- Switzerland
- I represent a company headquartered in Japan. The European regional affiliate is headquartered in the UK and the company has a local affiliates / offices in 15 further EU countries.
- Global
- Switzerland
- Denmark, but with affiliates throughout the EU
- France is the Headquarter but with affiliates operating in all EU memberstates.
- The company is headquartered in the USA but has country organizations in the EU member states
- JAPAN
- Switzerland
- My company is headquartered in France, but operates in all EU member states.
- Iceland
- SPAIN but with affiliates operating in several EU Member States
- Switzerland but we commercilaize drugs in the entire EU
- Outside EU
- switzerland
- The headquarter is located in JP, with affiliates in the US and affiliates in a lot of EU Member States operating in all EU Member States
- USA
- Switzerland
- Switzerland

- EU wide presence
- Headquartered in the US; operating in all EU member states
- United States but with affiliates operating in all EU Member States
- HQ in Belgium, but operating in all EU Member States
- The company I represent is headquartered in Denmark but is operating in all EU member states
- Switzerland but we are operating in all EU Member States with a significant affiliates and research sites in Germany

### Q 8: In which country is the association you represent located?

- We represent companies operating in all EU Member States.
- Switzerland
- Switzerland
- Switzerland
- European
- is representing European Patent Attorneys in all 38 member countries of the European Patent Convention; its secretariat is located in Munich/Germany

## Q12: Does your association mainly represent members of a particular industry, legal sector or academia?

- Independent
   Patent Attorneys
- IP managers
- Members of Industry and Legal sector are present in the Institute

Q 27: Regulation 1768/92/EC (now Regulation 469/2009/EC) was conceived with traditional chemical compounds in mind. In the meantime, biopharmaceuticals and products of recombinant DNA technology (such as proteins, antibodies, microbes, cells and cell lines, vaccines, viruses, DNA/RNA sequences or products for gene therapy) have grown in importance. In your opinion, does the present system adequately accommodate this technical development?

## -additional comments-

Questions have arisen regarding the correct scope of SPC availability for more complex
product situations stemming from evolutions of the biological and biopharmaceutical
sciences. It is normal for national courts to seek clarification and interpretation of EU laws with
regard to these. These questions have however been gradually addressed by the CJEU, which
has clarified in its decisions a very substantial number of these points which were raised to it.

Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.

- In addition to biopharmaceuticals and products of recombinant DNA technology, there are other types of innovative products not explicitly falling under the scope of the two present SPC Regulations. For example, medical devices or even biosimilars also play a decisive role in the continuing improvement of public health. In many cases, the development of these products is very costly. Moreover, such products often have to undergo safety testings, which are in scope and time schedule similar to authorisations granted under Directive 2001/83/EC or Directive 2001/82/EC. An exemplary medical device with a long development period is for example the cochlear implant (Cl), a surgically implanted electronic device that provides a sense of sound to a person who is profoundly deaf or severely hard-of-hearing. To sum up, it is very important that a new, additional SPC Regulation be created that provides adequate effective protection to the holder of patents of innovative products, which are on the "borderline" of falling under the present SPC Regulations, or which are not covered by the present SPC Regulations at all, but which suffer from loss of effective protection due to nationally required certification or authorisation procedures. In an ideal world, such a new SPC Regulation should be flexible and provide also adequate protection to future technologies.
- Not relevant for agrochemical sector.
- For example, Article 1(a) of Regulation 469/2009 refers to "combination of substances", while very often biopharmaceuticals are conjugates and there can always be discussion whether a conjugate could qualify as a "combination".
- Proteins, antibodies, microbes, cells and cell lines, vaccines, viruses, DNA/RNA sequences or
  products for gene therapy as well defined as a small molecule drug (one single INN name),
  and the combination product issue is also more or less resolved with medeva (disclosure level
  being the remaining issue). The big problem lies i the unclear judgments from the CJEU, at the
  moment this is particularly true for the Neurim judgment, so how new must a new medical use
  be to allow a new SPC for an existing product.
- Our working assumption was always that the Regulation did extend to cover antibodies and the like. This has now been confirmed by various CJEU and National Court decisions. We therefore see no need for a change to the Regulation.
- We have seen and agree with the comments that we understand EFPIA (of which we are a member organisation) will be submitting in relation to this question. The current Regulation, interpreted where necessary by the CJEU, has the flexibility to accommodate the above and future technical developments. Comment: Questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is normal for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these
- There is an great number of questions referred to the ECJ, a number which does not decline over the years, and the answers given by the Court obviously enough do not give sufficient guidance for the users of the system; this is a serious drawback of the existing SPC system. The regulations should be revised firstly to reduce the number of open questions in the application of those regulations and secondly the new technical developments (vaccines, biopharmaceuticals in general, plant protection products, the use of enhancers or adjuvants) should be taken care of with a new, clear and flexible wording of the SPC Regulations.
- There might be some uncertainty about the scope of an SPC with respect to
  derivatives/variants of biologicals, e.g. is the same biopharmaceutical molecule prepared by
  different means (e.g. different cell line or process, or even just a different manufacturer)
  considered to be the same 'product' under this Regulation? There appears to be for instance

a Dutch court decision concerning antibodies, reasoning that the regulatory requirements regarding biological medicinal products suggest that two similar biologics cannot be assumed to be identical and as a consequence the scope of the SPC should be limited to the specific product of the market authorization; a similar decision was given in a Norwegian appeal court dealing with a case concerning virus-based vaccines. Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.

- Scope of protection and adequacy product and patent claim may be difficult to meet
- We are not yet involved in biopharmaceuticals for EU
- It is not yet clear whether, under the current legislation, it is possible to strike a fair balance between the provision of: (a) an appropriate breadth of supplementary protection for innovators (in order to enable costs to be recouped and to incentivise further research and development); and (b) a clear boundary for the limits of supplementary protection, which boundary can ideally be determined at an early stage i.e. before significant investment is made in a "copycat" (biosimilar or "me too") biological product. However, the CJEU has not yet been asked to clarify how the relevant provisions (including Articles 3(a), 3(b) and 4) are to be interpreted in the context of "biosimilars" vs. an SPC to a biological product. Thus, it is too soon to say whether the current legislation adequately accommodates "biological" products.
- In principle yes will depend upon the interpretation by the CJEU
- The question is not relevant for the agrochemical sector
- Should be introduced in a separate legislation. Question is perceived as not relevant for the agrochemical sector.
- The idea of the SPC Regulation is based on the idea to extend the exclusivity position for a newly approved pharmaceutical substance. The basic patent was understood to be the substance patent, for which substanec the MA was given. If a dossier is approved for a new chemical entity, be it a new chemical derivative or a new amino acid sequence, if that was patentable (new and non-obvious) and was developed into a new drug, without the possibility to "bridge" that should be awarded with a SPC. If the approval was given without the need for a full application by relying on other data, than no SPC should be given.
- The current SPC regulations apply equally well for both traditional chemical compounds and biopharmaceuticals/products of recombinant DNA technology. The regulations, as currently written and interpreted by courts, do not discrimate against, favor or disfavor any particular technology or type of drugs. All molecules, whether traditional chemical compounds and biopharmaceuticals/products of recombinant DNA technology, require support of innovative SPC environment since signficant research and investment is required to bring these molecules from research to a final commercial product.
- Regulation 469/2009/EC is flexible enough to apply to emerging technologies. This is how it should be. The proper role of the CJEU is to interpret regulations, particularly when technologies progress. The underlying purpose of this regulation is clear compensate the MAH for patent term lost due to lengthy regulatory approval processes. It would be nonsensical to try to anticipatorily define every possible meaning of "product," particularly when there are other regulations (e.g., those defining the regulatory approval processes for medicines) that already define such in an evolving manner.
- they are sometimes covered by more than 1 patent per product
- In the context of the Plant Protection Regulation, there are also biological materials, new technologies such as RNAi, genome editing of plants etcetera are arguably not in scope
- The SPC Regulation, as interpreted by the CJEU, has demonstrated sufficient flexibility to
  accommodate new technical developments, including those in relation to biological and
  biopharmaceutical products. We believe that specific provisions for such technologies would
  risk being too prescriptive and would not necessarily cover future developments. In our view it
  is preferable for any further clarification which may be needed in the future to evolve
  organically through decisions of the CJEU.

- the SPC is granted for the specific "product"; it is unclear whether the scope of protection covers also "biosimilars". This would be needed to obtain effective protection for the SPC holder.
- In principle yes, but of course it depends on how Article 3 is interperted
- the issue is rather on the interpretation of the protection of the product by patent offices
- This is a question for the pharmaceutical sector
- Proven by the number of filed and granted SPC applications for biopharmaceuticals
- The technologies specifically listed in the question are adequately covered, but some developments in the crop protection area might not be. The development of technology is an on-going process which can be addressed by the CJEU if needed as new situations arise.
- At a high level, the system certainly accommodates these new developments. Vaccines presented challenges not so much in technology but in their combinations and resulted in caselaw needed to address them. Salts and esters of traditional small molecule compounds, which were considered, even needed caselaw to address them. We will now no doubt continue to see this same issue for biosimilars. Functional claiming in respect of antibodies is challenging the system, but either by addressing appropriate scope and/or the issue of "third party SPCs" this should be addressed. Overall, this is a very fine call as between "yes" and "no". Overall, I am not minded that opening the Regulation to amend it will necessary present a solution.
- We support comments from Efpia
- The biggest problem of the system is that the CJEU has invented something with no legal basis. Neurim seems a departing point. It has opened the Pandora box.
- Especially cells and products for cell-based therapies and gene therapies do not seem to be adequately covered. Also, in this field, there often only is broad functional language in the claim, which makes it difficult to assess whether the "product is specified in the wording of the claims" as required by the ECJ case law.
- The definition of "product" is not adapted Functional definition is necessary Name of the product object of the SPC should be adapted
- No legislation can predict future technology. The question is whether the Regulations, as
  interpreted by the CJEU, are able to adapt to new technology. We believe this to be the case
  since the CJEU addresses new technology situations as they arise and has generally given
  sensible decisions on this issue.
- The present system does not adequately accommodate these technical developments, but it
  is not a failing in the Regulations per se. It is essentially impossible to draft a regulation that will
  accommodate all future developments in technology.
- Questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is normal for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.
- Questions have arisen regarding the correct scope of SPC availability for more complex
  product situations stemming from evolutions of the biological and biopharmaceutical
  sciences. It is normal for national courts to seek clarification and interpretation of EU laws with
  regard to these. These questions have however been gradually addressed by the CJEU, which
  has clarified in its decisions a very substantial number of these points which were raised to it.
  Due to the nature of innovation, further circumstances that may require clarification could
  arise, but it should be left to the CJEU to clarify pending questions as they arise. Science,
  technology and innovation will always be running ahead of the legal framework and we

believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.

- It is crucial that the SPC system will allow covering new technologies as well, such as
  inventions of the biological and biopharmaceutical sciences. During the workshop of the MPI
  in 2017 one of the presenters showed the value of the existing system which allows evolution
  driven by case law to cover new technological aspects.
- The only real difference lies in the nature of the active substances in these classes of products and this can be accommodated applying current caselaw to the text of the SPC Regulation. Even that statement is a generalisation because some non-biological products comprise active substances that are in themselves complex mixtures (see, for example Copaxone, containing glatiramer acetate) so the need to deal with such active substances is not new.
- Questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is normal for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.
- Scope of protection is a key issue, which in turn depends on how generic/biosimilar products are approved for marketing - even more than new types of product. This is a regulatory issue, not a patent/SPC issue
- When applying the current SPC Regulation, it is important to be mindful of the particularities of biopharmaceuticals and recombinant DNA technology products. However, the basic structures of the SPC Regulation also allow an application for these modern pharmaceutical developments.
- The present SPC system excludes a number of important trends, most importantly combinations of drugs with medical devices. Such combinations often have to be authorized according to Directive 93/42/EEC and not Reg. 469/2009/EC. These combinations may not fall in the scope of the SPC directive due to non-compliance to Art. 2. This results in the rather unfair situation that a newly developed drug that has to be deployed from a medical device cannot obtain SPC protection merely due to its mode of administration.
- Questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is normal for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.
- The SPC regime already covers active biotechnological active ingredients and SPCs have been obtained for them. We expect the case law in this area to develop organically as technology progresses.
- The SPC regime already covers biotechnological active ingredients and SPCs have been
  obtained for them. We expect the case law in this area to develop organically as technology
  progresses.
- it could be useful to have some guidance/confirmation that the product in SPC-applications
  is described as INN where available, and for medicinal products or plant protection products
  where no INN is available, closely related to the identification of the active ingredient or
  combination of active ingredients as mentioned in the marketing authorization that is used as
  the basis for the SPC
- Questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical

sciences. It is normal for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Due to the nature of innovation, further circumstances that may require clarification could arise, but it should be left to the CJEU to clarify pending questions as they arise. Science, technology and innovation will always be running ahead of the legal framework and we believe it is illusory to try to deal with all emerging technologies through legislation, when the current Regulation provides for the flexibility to accommodate these.

• The SPC Regulation can also be applied to biologics, taking into account the particular characteristics of biologics when interpreting the regulation. The object and purpose of the regulation does not differ from biologic to small molecules. One example where particular consideration has to be given to the particular characteristics of biologics is Article 4 and the scope of protection (,...shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market..."). In case of biologics and DNA, any "generic" product is never identical, only "similar". Thus, Art. 4, in case of biologics, has to be interpreted that the "product covered" also covers biosimilars. This concept was already confirmed by the CJEU in Farmitalia (for small molecules in relation to salts and esthers). Hence, the SPC Regulation also protects biologics, if it is interpreted appropriately.

## Q 28: Please explain why you think the present system does not adequately accommodate biopharmaceuticals and products of recombinant DNA technology.

- It is often difficult to clearly designate a product in a claim and also to define a new chemical eintity.
- Issue related to the grant of SPC based on a patent which does not specifically claim the MA
  product. Issue related to the scope of protection of a SPC, in particular with respect to
  biosimilars of the product of the MA
- SPC not adapted for complex product such as gene therapy products which comprise a lots
  of components to form an API and potentially IPRs whereas only 1 patent can be granted an
  SPC
- Regulation 469/2009/EC was created as Regulation 1768/1992/EEC in 1992 with traditional chemical compounds in mind, i.e. 25 years ago. At that time it was certainly difficult to foresee future developments such as biopharmaceuticals and products of recombinant DNA technology. Accordingly, the definitions of Regulation 469/2009/EC were tailored to these traditional chemical compounds. This is in particular reflected in Article 1 (b) of Regulation 469/2009/EC, where the product has been defined as "the active ingredient of combination of active ingredients of a medicinal product". Since the present Regulation 469/2009/EC does not literally cover biopharmaceuticals and products of recombinant DNA technology, the applicant has to convince the Patent Offices of the applicability of Regulation 469/2009/EC. This creates more effort for both the applicant and for Patent Offices, and results temporarily in legal uncertainty for third parties. To sum up, Regulation 469/2009/EC does not need to be amended, but there is a need of a new, additional SPC Regulation.
- generic versions of an innovative drug still comprise the same chemical molecule whereas
  generic versions of biopharmaceuticals etc. differ from the innovative product because of
  the way they are produced it is therefore quite difficult to ascertain what is the real scope of
  a SPC obtained for a biopharmaceutical
- Insufficient to obtain protection of ONLY one specific compound biosimilars should also enjoy SPC protection
- Even the already existing language of the SPC regulations is ill-founded due to compromising at political level. The decision practice of the CJEU made it even worse
- As is the case, especially with DNA/RNA technology, the current SPC needs a first valid MA.
  This might not be possible due to prolonged research in in vitro models or animal (in vivo)
  models to ensure saftey and efficacy.

- In the case of recombinant DNA technology it is very difficult to define the product. This situation is not helped by CJEU case law. It should be sufficient to refer to the basic patent. The relevant test should be whether the claims of the patent are \*infringed\* and no further tests should be required.
- Patents concerning biopharmaceuticals and products of recombinant DNA Technology are claiming functional blocks of DNA sequences, but SPCs are based on specific drugs having a market exclusivity
- Because of the complexity of these large molecules (and even more so for combination products), it will be more difficult to assess whether there is a new product, whether the product is protected by the basic patent and whether an earlier SPC has been granted for the same product.
- Biopharmaceuticals and products of recombinant DNA technology are much too far away from the starting point of the Regulations with the traditional concept of chemical substances. Therefore the present system is not appropriate in relation to the new developments.
- Scope of protection may not be adequate and patent claim and product authorized may not fit
- Clear definitions (e.g. active ingredient, medicinal product) are lacking in the Regulation and thus renders its scope difficult to define. Note however that this also applies - to some extent to small molecules
- The actual system lacks definition on basic matters, wich allows member states to take differnt approaches on various subjects like second uses. For more complicated matters, the gap between the actual system and interpretation by National Offices broadens.
- often products are not clearly identified and seem sometimes not the same for the different couuntries
- The system struggles with multi administration treatments (e.g. vaccines and combination therapies)
- The scope of protection, Art. 4, seems to be inadequate/unclear with regard to biopharmaceuticals
- Even though not an expert, there seems to be lack of guidance. Also due to the complexity of each case sometimes courts issue decision based on completely different grounds.
- usually, in the biotech and gene therapy field more than one technologies covered by more
  than one patent are involved in the therapy. The current SPC regulation forces company to
  choose only one component of such technologies for the SPC application, thus reducing the
  overall protection of the basic patents.
- Due to all the paperwork and documents which has to prove and show causing a delay in research and development of a medical product
- same as before
- In the context of the Plant Protection Regulation, the SPC regulation does not refer to the relevant Regulatory regulations.
- see my comments to the previous slide
- The SPC Regulation does not always apply in accordance with its policy goals in the biological field. It will not always extend protection for innovators and at the same time it can allow SPCs to be granted based on third party marketing authorization even where the development work carried out is unrelated to the patentee.
- The requirements for 'protected by the patent' are difficult to be fulfilled, for complex biopharmaceuticals and for 'chemica' compunds falling under a broader formula claimed
- The original SPC regulation as it was codified could be interpreted in multiple ways because it could not anticipate adequately and unambiguously all the possible cases (see e.g. combination products) so CJEU decisions were needed to clarify them. This has been a long

story and still further developments can be expected. The same story will happen to biological products expectably.

- No developped models to evaluate
- Because of the existing case law which causes legal uncertainty
- The literal interpretation of the definitions of the regulation, e.g. of a "product" may be difficult to fit to emerging fields of medicine
- Because Regulation 469/2009/EC raises many doubts in the interpretation of Art. 3.
- In a patent, an antibody may be only defined by its CDR encompassing several antibodies and meanwhile the authorized antibody may be not clearly described.
- The definition of "product" in 469/2009 does not work well for biopharmaceuticals, in particular in providing clear protection against biosimilars
- The current interpretation of Article 3(a) from the CJEU (Medeva, Lilly, Actavis) is too crude to accommodate these kinds of technological developments. They will need a more nuanced approach, possibly on a case by case basis. However this supports leaving the current Regulation as it is (without amendment) and then to allow the interpretation to develop through the caselaw as issues arise. It is not possible to anticipate them all at this stage and to allow for them in an amended Article.
- Biopharmaceuticals are based on a different concept than small molecules and might thus require a regulation of their own
- Since the "Definitions" of the Regulation it is clear that the same has been devised to address issues related to classical compounds. There are no clear provisions on how biopharmaceuticals could be considered, since the aspect of "active ingredient" won't be central anymore.
- vaccines can present a particular difficulty for the present SPC regime
- Adequate protection in the field of biosimolars is needed
- Many reasons: a) Protection for different salts available. b) It does not define product, biosimilars are not generic, etc.
- Artcile 3a) as construed by the CJEU makes very difficult to get the appropriate SPC protection most Biopharma products deserve.
- Especially cells and products for cell-based therapies and gene therapies do not seem to be
  adequately covered. Also, in this field, there often only is broad functional language in the
  claim, which makes it difficult to assess whether the "product is specified in the wording of the
  claims" as required by the ECJ case law.
- development times of biopharmaceuticals are so much longer and with much more uncertainty that the final product is not protected long enough; development cost are much higher also; 15 years of market exclusivity should be available;
- No further comment
- I wonder if the people who drafted this survey have any real knowledge of the issues. Whether
  or not something is a product of recombinant DNA technology is irrelevant the key is what
  the copier must do to get onto the market how similar must he be to the originator's product
   easy to determine for "chemicals" not so easy for biologicals
- Article 4 of Reg. 469/2009 states that the scope of the certificate extends only to the product subject to the MA. Biopharmaceuticals that differ slightly in structure or in the way it was opbtained may, however, provide the same pharmaceutical effect. If the certificate is limited to the a certain form (subject to the MA) and a biosimilar product is not comprised by the scope of the SPC, the SPC is useless in preventing entry of biosimilar products onto the marked. Hence, the SPC regulation is not an incentive for developing biopharmaceuticals
- definition of "product" not adapted functional definition is necessary name of the product, which is the subject matter of the SPC, should be adapted

Biopharmaceuticals are often claimed in part with functional technical features, and the
undifferentiated application of early small molecule-based case law (e.g. Medeva) to such
cases is inappropriate and as such as it ignores the importance of functional features
necessary to define biopharmaceuticals.

Q 30: In your opinion, what specific changes or amendments are needed with respect to Regulation 469/2009/EC and/or Regulation 1610/96 in order to better accommodate these technical developments?

- Clarification on the meaning of a product according to art. 1 b) (definitions) and consequently on the interpretation of Art. 3 a) and b) should be made. Clarification about the interpretation of articles 4 and 5 are also needed
- Be more flexible in determining which patent for a complex product (eg gene therapy product) can be extended through an SPC
- As a matter of fact (and this applies also for conventional pharmaceuticals) the Regulation should be abolished and replaced by a Patent Term Extension system as is known in other major jurisdictions (USA, Japan, Russia).
- The SPC regulations have to move again more to patent law. The decision practice of the CJEU has developed more and more into the pharmaceutical/regulatory language and did not consider basic principles of patent law. This is, however, not only the CJEU's fault but mainly enabled by inappropriate, inconsistent and sometimes cortradictory language of the regulations
- A chance for a promising DAN/RNA technology to gain a SPC even without first valid MA. This might be accomplished with a defined set of data concerning efficacy and saftey in different models to grant a SPC. In my opionion such terms would help to develope and help reasearchers to actually work and also gain something from the research that is accomplished by them. Especially for Universityas or other open research foundations, it would be helpful to earn something with their patents as phamaceutical companies are more interested in further developed medicinal products and will only take liscences if the patent is still valid for a longer time and the medicine is rather promising.
- Article 4 should be broadened. The relevant test is whether the basic patent is infringed, and obviously there should be some relation to the marketing authorization.
- provide for a better product definition provide for a better link with regulatory legislation and findings of regulatory authorities, who are more equipped to judge whether a biopharmaceutical product is indeed a new active substance and not a (minor) variation. It is not without a reason that in article 2 of the present SPC Regulation reference is made to Directive 2001/82 and 2001/83
- A new definition of the term "product" in order to give the applicants the proper protection for their inventions.
- Type of patent protection available for the relevant market products shall be taken into
  account when deciding on what an SPC may be granted and for which scope, keeping in
  mind what the SPC protection should provide for the originator Scope of the SPC protection
  should e.g. be revisited taking into account possible easy workarounds Combination,
  product by process and use claims have to be considered as well
- Clarification of the requirements for filing a SPC application, Clarification of the scope of the SPCs (e.g. for combination products, new uses, etc.). Especially for combo products, I am not sure that last decisions from the CJEU really comply with what the Legislator had in mind, Same with new uses, last décisions seem to contradict what is provided for in the Regulation, Documents needed for filing at the patent offices should also be harmonized.
- Regular guidelines on examination and interpretation may have to be issued by an European Authority, besides of the Regulation wich may be more difficult to amend. Reference

- guidelines are standard procedure with other IP related offices, like EUIPO, they provide certainty to the user on how the matter will be prosecuted.
- At the very least the Regulations should be amended to clarify the scope of protection conferred by SPCs for which the product is a biotechnological active ingredient
- As already mentioned, the recombinant DNA therapy would require more than one patent in order to be put into use. Therefore, the SPC would reduce the overall patent protection.
- Article 3 (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate Article 7. 5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate. Article 13. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.
- the scope of the SPC should be clarified. It should cover the "product" and derivates thereof covered by the base patent.
- Ensure that innovators of such products are able to obtain SPC protection where marketing authorization is over 10 years after patent filing, without allowing such rights to third party patentees who are not involved in the development of the authorized product.
- Legal definitions of terms used in the Articles, such as "protected by" etc.
- Better explanation of the requirements of Art. 3 Regulation 469/2009/EC.
- A team of technical experts should meet in the context of the European Commission and discuss together with legal experts the best way to amend the Regulation.
- Biopharmaceuticals and nucleic acid-based therapies are often claimed using more functional features than traditional "small-molecule drugs", which leads to problems of interpretation of scope. It would be helpful if there was a possibility in all EU countries to more clearly define the protected subject-matter in an SPC application, over and beyond what follows logically from the patent claims and marketing authorization. In particular, it would be beneficial if the applicant himself could provide a definition in the form of a "claim", which could then be drafted broadly or narrowly depending on the balance between "risk of invalidity" and "adequate protection of functional equivalents".
- More clearly define what is the product of the SPC More clearly define when a product is protected by the basic patent
- Definition of the product to be amended
- market exclusivity of 15 years calculated from Marketing Authorization should be available
- Actually, I think it could be dealt with by evolution of case law. The Farmitalia case (1997)
  dealt rather badly with issues of scope of protection (it was an article 3a question which got
  confused, by the ECJ, with Art 4 issues. The real need is to have CJEU sitting with technical in
  drug approval and legal experts in patents, so that they did not make so many silly mistakes.
  Changing the law would lead to change but probably would mean swapping one set of
  unknowns for a further set of unknowns.
- Article 4 of Reg. 469/2009 could be amended to specify, that "the protection conferred by the
  certificate shall extend only to the product covered by the authorisation to place the
  corresponding medicinal product on the market including any equivalent pharmaceutically
  acceptable forms thereof that provides the same therapeutic effect" In the alternative, an
  independent Article applicable for biopharmaceuticals specifying the same as above could
  be introduced.
- functional definition is necessary
- Article 3 (a) of the SPC regulation 469/2009 should be amended to more explicitly define
  when the product of an MA is "protected by a patent". CJEU case law on this point is
  nebulous, often defining one in unclear term with one or 2 further unclear terms. This could be
  alleviated by more clearly setting the standard in the regulation itself.

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU

# Q 31: Do you think that the current SPC Regulations have encouraged "evergreening" strategies? - additional comments-

- The use of the word "evergreening" is not helpful as there is no shared understanding of what this means. SPCs are based on patents and by their very nature are meant to extend the patent term for the marketed product for a finite and limited period of time. It is not clear what is meant by linking the granting of SPCs to "evergreening" and there is no basis are aware of to suggest the SPC regulations have encouraged any such (undefined) strategies. find the question contains unwarranted bias given that it offers two options for saying "yes" and only one option for saying "no" and that option is limited to a conditional `no'.
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By asking the question in this vague way, the survey gives credibility to common misconceptions.
- We do not believe that the SPC Regulation has resulted in "ever greening" (at least by what
  we understand by this term in the absence of a definition). There is no option to definitively
  say "no" in the list above and there should be as this is the option that would have been
  selected rather than saying "not substantially".
- Due to potentially unanswered questions in the case law, there may be an unjustified proliferation of SPC applications for every small modification of the product.
- The uncertainties deriving from the broad language of the SPC regulation have made it possible for originator companies to make (legitimate) use of it aiming at extending monopoly on the market as much as possible.
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.
- There is a 5 years cap for the SPC term already set in the SPC Regulation- consequently, no
  further extension beyond this is possible. It has to be underlined that agrochemicals
  companies develop products for market needs.
- Evergreening with SPCs is an issue especially for combination products!
- It is inappropriate to consider SPCs or any additional patent protection as "evergreening" as they cannot be granted unless the patentability criteria are met (novelty, inventive step and industrial applicability). An SPC can only be attached to a valid patent. As pharmaceuticals are regulated products and manufacturers are required to demonstrate their quality, safety and efficacy before placing them on the market, the purpose of SPCs is to compensate for the lengthy development process and the time needed to undergo the regulatory approval procedures.
- But this will always be attempted in any system there is more evergreening going on in the patent system than in the SPC system (for now)
- I am not aware of any evidence that the SPC Regulations have encouraged "evergreening" at all.
- We have seen and agree with the comments which we understand that EFPIA will be submitting in response to this question. Our preferred answer is simply 'no' and it is regrettable that this option is not provided. Comment: This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the

question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.

- Only looking at the SPC Regulation, both the SPC term and the number of SPCs per product are capped. SPC term has a cap at 5 years; only one SPC per product possible, not a second one. All 4 conditions for obtaining a SPC (Art. 3a, 3b, 3c, 3d) provide a balanced system. Even if SPCs are obtained for later developed (different) products, the scope of protection is smaller.
- The answer should be an unqualified 'no'. It is not clear what is meant by 'evergreening'. The SPC Regulation has important, adequate 'safe guards' in place, such as the 5 year maximum term
- This question is very biased in nature. The use of the word "evergreening" is objectionable as there is no shared understanding of what this means. SPCs are based on patents and by their very nature are meant to extent the patent term for the marketed product for a finite and limited period of time. It is completely obscure what is meant by the link from SPCs to "evergreening" and there is no basis at all for any statement that the SPC regulations have encouraged such (undefined) strategies. Furthermore, it is biased that there are two options for saying "yes" and only one option for saying "no" and that option is not even a straight no, but a conditional one.
- No
- The uncertainties in the SPC Regulations have made necessary a high number of referrals to the CJEU for the interpretation and clarification of the law. CJEU decisions may seem to be drafted as generally applicable to later cases. However, the wording of the CJEU decisions are too often restricted to specific conditions of the case, which have made difficult the generalisation and have required additional referrals for later cases. CJEU decisions take generally a year or so plus the time of the national court decision. These uncertainties and the long time needed for clarification have encouraged evergreening strategies, since even if the originator ends losing the case in last instance, they were able to take advantage of the uncertainties and at least delayed the generic entry which resulted in their benefit. At least now several issues have been clarified though it was at the expense of many referrals.
- These strategies are made possible by the wide formulation of the regulation.
- My answer is actually "no" (i.e. without the qualification "not substantially"). However, it is important to note that: there is no commonly-accepted definition of "evergreening"; and so the more appropriate question is whether the SPC system adequately takes all interests into account (which question has already been asked and answered).
- We wish to answer "no, not at all", but this option is not present
- There is a 5 years cap for the SPC term already set in the SPC Regulation- consequently, no
  further extension beyond this is possible. It has to be underlined that agrochemicals
  companies develop products for market needs.
- SPC term has a cap at 5 years; only one SPC per product possible, not a second one. All 4 conditions for obtaining a SPC (Art. 3a, 3b, 3c, 3d) provide a balanced system. Even if SPCs are obtained for later developed (different) products, the scope of protection is smaller.
- Certainly, whenever products are protected by additional SPCs (on indications or compositions or combinations) whenever no full new application for regulatory approval and hence no full approval process was necessary.
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no". There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. All products that obtain SPC protection under the current Regulation have a well defined regulatory pathway that needs to be supported by R&D investments and innovation. By even asking the question in this vague way, the survey gives credibility to common misconceptions that SPCs protect non-innovative R&D.

- This is a very poorly written question and not the first that I've seen in this survey. First, it assumes that the reader knows what evergreening" means (the fact that the word is in quotations indicates that even the author of the question does not know what the word means), and it assumes that there is such a thing as "evergreening" (with which I patently disagree). Additionally, the question does not permit the respondent to state categorically "No" with no qualifiers. When a patent expires, the invention claimed in the patent becomes dedicated to the public and may be copied by others. Furthermore, an MAH may only extend ONE patent per product with an SPC, so the number of patents covering a particular product (beyond "1") is really totally unrelated to the availability or purpose of an SPC to compensate the MAH (who spent the time and money developing the new medicine) for the patent time lost in that endeavor.
- There is no connection whatsoever between the SPC Regulation and so called 'evergreening' strategies. The answer to this question is 'Not at All' and I'm concerned that this was not included in the response options.
- We think the question as well as the possible replies are biased. The answer is NO.
- The preferred answer would be "NO." However this is not an option provided by this
  questionnaire. While it is unclear what is meant here exactly with "evergreening", the
  assumption apparently underlying this question, that there are evergreening strategies, is
  strongly refuted here.
- Our answer to this question is 'NO'. It seems rather strange that this option has not been
  provided above, as it could lead to a misleading outcome. The purpose of the SPC
  Regulation is to compensate the patent holder for erosion of patent term due to
  development and regulatory timelines. This cannot in any way be considered as
  'evergreening'.
- evergreening would exist independently of the SPC regulations
- Evergreening is a perception, not a strategy. What is described as "evergreening" is nothing more than the protection of improvements of products by patents, which improvements are only patentable if they satisfy the patentability criteria. Once a patent on an active ingredient expires (even after SPC), it becomes available to all, including generic companies. Only the further patents on improvements are not yet available, meaning that generic companies do not yet have access to the latest (most-improved) version of the product, but the original one has become available. Moreover, most patents on improvements cover new uses of the product, which themselves are not the subject of SPCs, so SPCs have no effect on the practice of protecting improvements.
- Not really. Reimbursement authorities not granting premium prices to products with marginal
  added therapeutic value -, and competition combined have worked quite effectively to
  reduce the attractiveness of me-too products. You see this reflected in research strategies of
  big pharma.
- Especially for combination products and new formulations
- What is meant by "evergreening" in this context? If it means that multiple patents are filed to cover a single pharmaceutical product and extend market exclusivity for that specific product, then SPCs have had no effect. If obtaining an SPC is in itself an act of "evergreening" then the answer of course is yes because SPCs were not available before the SPC regulation was put in place. Further the question is biased because there is no option to say "Not at all". The question assumes that some evergreening has been encouraged.
- This question is biased the answer we wish to give is "No, not at all".
- I have answered "No, not substantially" as it is the most negative response. The answer "no" should have been provided and I would have selected it. The word "evergreening" is undefined and tends to be viewed as referring to unjustified/unlawful monopoly extension and so is negative. If that is what is intended here, it would reinforce my desire to say "no" to this further still.
- I would like to answer the question with a straight "NO", as SPCs have nothing to do with "evergreening strategies". To obtain a basic patent or an SPC, an applicant must comply with the provisions of patent law and the SPC regulations. This has nothing to do with

"evergreening". Besides, it is not defined what "evergreening" is supposed to mean in the context of this survey.

- The SPC Regulation has by no means encouraged for evergreening strategies. Therefore, the answer should be "No" instead of not substantially!
- The answer is NO. This alt is missing. We support Efpias comments.
- The problems of the definition of product has not been resolve. On palmitate pariperidone are different opinions across different offices. Neurim is the biggest ground for uncertainty.
- Our answer would be "No" or "Absolutely not". Indeed, there is absolutely no relation between
  the "evergeening concept" and the "well framed/defined" objectives of the SPC regulation.
  But this option is not given in the suggested answers. This question seem to be fully out of
  context.
- The answer we wish to give is no, not at all. To have asked the question without this option shows bias. No one knows, precisely, what evergreening means, particularly in the medical area. We refute the idea that evergreening exists for medicines since they are generally protected by only one or at most a small number of patent rights in practice. All these rights have a finite duration and so medicines eventually become generic in every case.
- This is not a question concerning the SPC system; other strategic decisions; what is evergreening supposed to mean, anyway?
- This question is biased. SPCs are applied to extend the basic protection for a new molecule or combination. This has nothing to do with "evergreening" but compensates for effective patent term loss due to lengthy development and approval process for new drugs including combinations.
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.
- The question is not self-explaining as the term "evergreening" is not defined. It lacks concrete examples of what is meant.
- Far greater drivers of evergreeening strategies are the availability of regulatory data/orphan
  protection for minor product variants and combination products see, for exmaple, the Tobi
  Podhaler which has evergreened tobramycin nebuliser products against generic competion
  for almost 20 years.
- Our answer is "no" without qualifications. This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.
- By making second medical use inventions subject to SPC protection. This is, however, beneficial to the patients and to society because it shortens the time that would otherwise

have been spent on identifying novel active ingredients and finding a suitable formulation of a new drug

- The questionnaire unfortunately does not explain what is understood by "evergreening" strategies. It is not a legal term, either. We note that the term is used in discussions with varying but vague substance, and typically with a bias against the research-based pharmaceutical industry. We therefore query whether it is appropriate to use this term in a survey like this one, as it creates the impression of bias. In any event, the SPC Regulation is designed to protect and encourage innovation in the pharmaceutical industry.
- We perceive SPC as a common tool to prolong market protection and not genuine innovation
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.
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- The term "evergreening" is not defined in the survey, and there is no universally accepted definition of the term. If the term is interpreted to mean prevention of generic/biosimilar entry the answer is very clearly: No. The duration of an SPC is maximally 5 years. After expiration of the SPC, the subject-matter protected by SPC can freely be copied by anyone. Thus, the ability to retain exclusivity for ever is based on a misconception.
- The uncertitnies deriving from brad language of the SPC Regulation have made it possible for orginator companies to make (legitimate) use of it aiming at extanding monopoly on the market as much as possible.
- The current SPC Regulation contains a number of significant ambiguities and uncertainties in the requirements for obtaining an SPC. In particular, Articles 1 and 3 of Regulation 469/2009 include numerous terms and definitions which are open to differing interpretation. As a result of the uncertainties, originator companies have been able to play the system in order to obtain SPCs in situations that spirit of the Regulation did not originally intend to allow, or obtain SPCs having longer duration than was originally intended. Numerous examples of this practice exist. One such example is where uncertainties in the meaning of Article 3(b) and (d) have allowed the Austrian Patent Office to grant SPCs based on Type II variations of an existing marketing authorization. Essentially this means two SPCs are being granted based on a single MA. A CJEU referral is likely to be required to overturn such practice, causing delays and cost to generic market entry. Another example is in the case of the drug product amlodipine / valsartan, where the originator company has self-revoked their key combination patent, on which an SPC was granted, in favour of a divisional patent, and have applied for a second SPC based on the divisional (arguing that the original SPC never existed by virtue of the revocation). The brand is essentially shielding their patent from scrutiny by generics, and the current SPC framework arguably allows this (without a CJEU referral on this point).
- SPC term has a cap at 5 years, only one SPC per product possible, not a second one. All 4 conditions for obtaining a SPC (Art. 3a, 3b, 3c, 3d) provide a balanced system. Even if SPCs are obtained for later developed (different) products, the scope of protection is smaller.
- First, the Supplementary Protection Certificate (SPC) regulations prolong the market monopoly
  of originator companies, and delay generic competition which otherwise plays a critical role
  in reducing prices of medicines and providing a wider range of options for procurement by
  public health agencies. Although SPC is authorised by regulatory authorities, the
  consequences and effects of SPC functions in the same manner as a patent term extension,

which is beyond the obligations of international trade agreements and has been considered as detrimental to public health. Secondly, companies apply SPCs as an additional instrument to extend market monopolies. Companies link the strategy of patenting minor changes to old medicines (such as combination regimens or derivatives of old medicines) as closely as possible to applying for a SPC on those minor changes. If SPCs are granted on those derivative features of medicines or insignificant modifications of old formulations, the strategy of "evergreening" market monopolies through secondary patenting is extended and reinforced through the SPC system. Therefore, we consider that SPC regulations encourage "evergreening" strategies.

- SPC term has a cap at 5 years, only one SPC per product possible, not a second one. All 4 conditions for obtaining a SPC (Art. 3a, 3b, 3c, 3d) provide a balanced system. Even if SPCs are obtained for later developed (different) products, the scope of protection is smaller. At the end it would be more precise to say no, not at all.
- two situations: 1. either SPC protection which was obtained based on an earlier approved medicinal product also protects a later medicinal product; then the proteciton time also for the later product is limited due to teh maximum SPC-termsunder Art. 13 of the SPC-Regulations; OR 2. the later approved medical product constitutes a new product in the sence of the SPC-Regulations and becomes subject of its own SPC-protection; in that situation the earlier approved medicinal product won't be protected any more by the earlier SPC and therefore no "evergreening" effect since third parties can compete with the earlier approved medicinal product, even if the later approved product is still protected by the second SPC
- This question lacks balance and objectivity and is highly biased. First, while it provides two nuances of "yes", it provides no option to only answer "no", let alone an option or a comment box to refute the basic assumption underlying the question, that there are "evergreening" strategies. There is neither a common understanding nor a definition of what "evergreening" might be and therefore the question is also unclear. The purpose of SPCs is to extend patent protection subject to the various conditions provided in the SPC Regulation. By even asking the question in this vague way, the survey gives credibility to common misconceptions.
- We consider this a biased question. In substance, the SPC Regulation fosters innovation in the pharmaceutical industry. Right holders may perfectly legitimately avail themselves of the protection offered under the SPC Regulation to ensure return on investment into such innovation.
- Only looking at the SPC Regulation, both the SPC term and the number of SPCs per product are capped. SPC term has a cap at 5 years; only one SPC per product possible, not a second one. All 4 conditions for obtaining a SPC (Art. 3a, 3b, 3c, 3d) provide a balanced system. Even if SPCs are obtained for later developed (different) products, the scope of protection is smaller.

## Q 32: In your view, what specific aspects of the SPC Regulations have encouraged "evergreening" strategies? Please explain.

- The Neurim decision is a typical example of a bad decision which may have been considered as a "one off" by the judges of the CJUE but turned out to be a disaster interms of legal uncertainty for third parties
- Due to unresolved issues concerning the interpretation of Article 3(d) of the SPC Regulation it
  is not clear whether SPCs for new formulations could be obtained. There is a concern
  regarding compatibility of Neurim on the one hand and Pharmacia (C-31/03) and Yissum (C202/05) on the other.
- The wording of the SPC regulation is rather vague. For instance, it has allowed multiple SPC, 'negative' SPC, SPC on second medical uses (which are many for some products), etc.. In addition, calculations of SPC are based on the date of the first marketing authorisations (MA) this allows patent holders to 'play' with the time in order to get one as long as possible SPC.
- unclear definition of "product", "1st Marketing authorisation in EU", filing of multiple SPCs in the same Country for one product

- It depends on what you consider evergreening and what you consider fair compensation for further developments. Certainly The Neurim judgment will open up for companies probing for where the line is drawn for SPCs on 2nd medical uses (is shift from veterinary to human necesarry, or just different indication/disease, or is it enough to have a new dosage regime or the like). Also the Medeva judgment opens up for a grey area, where the combination product may or may not be inventive compared to the mono-product, and is it then fair to have a patent extended when the invention does not lie in the actual combination.
- 1) The definitions of product and basic patent are too vague. Derivatives or (minor) variations of products for which an earlier patent/MA/SPC have been granted are not addressed. 2) The definition of the first MA is not clear enough. A link should be established with Directive 2001/83, especially article 6 and the concept of the first, initial (global) marketing authorisation 3) Article 13 links the lifetime of the SPC to the date of grant of the first MA. The later the first MA is granted, compared to the date of patent application, the longer the lifetime of the SPC will be. When a MA will be granted, depends on the date the application is filed and the speed with which the applicant pursues the proceedings at the national MEB/EMA level. Especially if the pharmaceutical company already has a product on the market, protected by patent/SPC and/or data exclusivity rights, there is not always a need to immediately file the MA application for the next generation of such product. It pays to file an MA application for such next generation at a relatively late stage, when the exclusive position of the pharmaceutical company regarding the first product is coming to an end.
- SPCs based on 2nd medical use claims
- More SPC on the same patent covering different products (combination)/SPC on use
- Unclear scope of the SPC: A5 says that the SPC confers same rights and obligations as the patent but, to some extent, CJEU has interpreted A5 as meaning that the SPC has same scope as the patent (despite A4) Same with unclear definition of medicinal product and active ingredient However the principle at the basis of the SPC should better be taken into account by Courts: the patent is the reward for an invention and the SPC is the reward for a approved drug, thus the SPC (scope & filing) cannot be "separated" from the market authorization. This deviation is also seen with the 6-month extension for pediatric studies, some SPCs for whihe no pediatric studies have been made have benefited from the 6-month extension.
- As I explained it in the comments to the previous question, the broad wording of the SPC
  Regulations and not foreseeing the potential specific situations at the time the regulations
  were drafted has lead to several uncertainties and has required several clarifications from the
  CJEU (e.g on calculation of duration of SPCs, possibility of multiple SPCs for one product, SPCs
  for combinations,..). The Neurim case may be used for evergreening strategies, but judge
  Arnold has already indicated his intention to refer a question to the CJEU for clarification.
- The phrasing of the Regulation is very unrestricted. Thus there are several possibilities to cover the product with different SPC. This is especially true for products that are as complex as Biologicals.
- several SPCs granted to different entities which sometimes are linked
- multiple SPC applications for one product; affiliates of the same legal entity appear as applicants; multiple SPCs for one basic patent for combination products;
- It allows a longer period in which to develop switching opportunities to new formulations
- Allows for second medical use and combinations where little or no inventiveness in combination per se
- insufficient definition of "product" term
- The most relevant aspect herein is the idea that an SPC could be given to an indication patent, or rather to any new indication patent, when the indication lies outside of the scope of the first indication patent. Thereby opening the door to evergreening, because indication patents are quite easily to get granted at the EPO for example on a specific patient subpopulation, but can be a nightmare to be 'carved out'. The second most relevant aspect is the possibility to get new SPCs on combination products, even though each single compound had benefitted from its own SPC based exclusivity already. The third tool to

evergreen is to transfer some rights to a daughter Company, which happens to have a patent reading on the product, and make them apply for an additional SPC.

- 1. Date of first authorization 2. Multiple SPC for different product by same patent
- The ambiguous formulation of Article 3 Regulation no. 469/2009
- more than one SPC for an API. The system is being abused.
- Now SPCs for new formulations and new indications of a known substance are possible. The
  costs for a new registration are fairly outweighted by the cost return by longer exclusivity
  periods
- The ability to obtain an SPC for a combination production of known active substances
- The different interpretations of the Regulation by each national office as well as the different practical requirements in order to check compliance with all the requirements of Art. 3.
- a slight change of molecule gets SPC granted: e.g. metabolite, Racemate, etc. allthis can be brought into combinations too, what is again protecting the old combinations. This is not the idea of SPC Regulation.
- applying for multiple SPCs for the same INN. in most of national offices there is no obligation
  for the applicant to inform of previous SPCs nor there is an option for third parties to present
  observations to inform about inaccuracy in the application documents
- To the extent that they protect new derivatives or new formulations of existing active ingredients, this is a step too far. There needs to be a fair balance between protecting innovation and encouraging generic production. The difficulty is that the Regulation is drafted so as not to discriminate between different types of innovation. However, as a matter of policy, there is argument to draw a line between a new product or a new use on the one hand, and a new formulation or new derivative of an existing product for an existing use on the other.
- The overall concept of protection will always encourage some companies to try to exploit innovative protection for the longest possible term
- The language of the SPC Regulation is rather vague.
- The first mean has certainly be that of divisional applications.
- Obvious combinations though recent case law is still developing
- multiple SPC applications on different patents with tiny variations. Have seen "Neurim" used to try and claim SPCs on products that are not original.
- That the definition of product is not clear and the Neurim decision from the CJEU. Also the
  erratic ractice of patent offices that do not review that all requirements are met.
- 1. The definition of product is clear in the Regulations. However, the recitals allowed that different salts obtained SPCs despite being the same product. 2. Neurim decision has risen some possibilities for evergreening new formutations, new indications, etc.
- Extension of exclusivity creates more difficulties to introduce generics in the market
- The possibility to obtain successive SPC protection for a product and that product in combination. The possibility to apply for more than one SPC for a product via different corporate entities.
- Patents should protect fundamental discoveries/inventions. Subsequent small modifications should not get the same kind of IP protection. After all, patents are both an incentive to innovate as well as an entry barrier for new entrants.
- mostly lack of clearer definitions
- That only up to 5 years of extension of the patent is offered by the SPC Regulation. This is because it easily takes more than 15 years to identify, test and develop a new drug and performing clinical trials. This is more expensive and more time consuming than testing any therapeutic effect of a known drug for a new indication. Therefore, the economic gain for

developing an entirely new drug is smaller because it is more expensive and also, the potential protection period (20 years from filing + up to 5 years extension) will probably expire sooner after the product has been marketed compared to the situation of an already known drug

- There are several issues which are open to interpretations such us several SPC by different companies based on the same marketing authorisation, several SPC by same company for the same product, formulation, indications etc, requirements to entitlement to SPC for generic claims, combination products
- The language od the SPC Regulation is rather vague. For instance, it has allowed multiple SPCs "negativ" SPCs. SPCs on second medical uses (which are many more for biological products) etc. In addition, calculations of SPCs are based on the data of the first Marketing Authoristaion (MA). This allows patent holders to "play" with time in order to get an as long as possible SPC.
- As a consequence of unclear statements and definition in the text and the not clear decisions in case low even small modification in the product can start a new SPC filing...
- See answer to previous question. In many cases it is the uncertainty in the interpretation of the SPC Regulations that allows the evergreening strategies. This is not only as a result of the specific wording of the SPC Regulations, but also as a result of numerous unclear decisions handed down by the CJEU. These decisions often try to solve one issue of interpretation, but end up creating further uncertainty (because they introduce tests which themselves include ambiguous terms), but also because the decisions only go as far as is necessary to answer the specific question that is asked, rather than giving complete guidance. This is exemplified by the numerous referrals around the meaning of Article 3(a) of Regulation 469/2009.
- Firstly, the SPC Regulation itself provides a prolonged market monopoly even after the patent expires on a medicine, which serves no purpose except to generate additional monopoly revenues on behalf of the patent holder. More specifically, the scope of SPC Regulations as defined by Article 2 of Regulation 469/2009/EC is broad and enables companies to devise and implement "evergreening" strategies. Article 2 defined the scope of protection of SPC as applicable to "any product protected by a patent". The definition of "product", according to Article 1 of Regulation 469/2009/EC, is the active ingredient or combination of active ingredients of a medicinal product. This definition was further expanded by Regulation 1610/96/EC, in which the Paragraph (14) of the Preamble states that "the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them". Both the "combination of active ingredients" and "derivatives (salts and esters) of the substance" under the above two regulations are problematic. Both could be potentially challenged and ruled as lacking of inventiveness if a patent applicant sought patent protection for a derivative or combination. Case law in Europe has demonstrated that trivial changes of known substances might not receive patent protection. For instance, the decision in Teva UK Ltd & Ors v. Gilead Sciences Inc (2017) EWHC 13 (Pat) ruled out the patentability of a combination of active ingredients for lacking of inventiveness according to patent law. In other countries, such as India, an application for patent protection on derivatives might be rejected for failing to satisfy the requirement of 'inventive steps'. The attempt to patent the mere combination of two known substances, or derivatives of known substances, has been long considered as a critical and central strategy for pharmaceutical companies to seek "evergreening" of monopolies. Allowing SPC protection on combinations and derivatives of medicines with granted patents sends a signal to companies to continue apply evergreening strategies. Finally, SPCs create an additional burden upon regulatory bodies to grant SPCs based on patent status, wherein the primary role of a regulatory body should be to assess and ensure the quality, safety and efficacy of medicines. Technical standards and competence to assess patents is wholly unrelated to those used to assess medicine quality, safety and efficacy, thereby creating and unjustified and confusing burden to the regulatory authority.

Q 33: In your opinion, which of the following development activities should be covered by SPCs? -additional comments-

- Provided that all of the conditions of grant set out in Article 3 are satisfied, then the
  development should be covered by an SPC.
- It is not clear whether this question is asking whether the four categories listed fall within the scope of an SPC. That is generally the case already under the current Regulation. Or whether the question is asking if active ingredients in these four categories should receive SPCs in which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- Any of these developments may contribute to the improvement of public health.
- To the extent that an innovation within any of the categories above is covered by a patent and subject to a marketing authorisation, then an SPC should be granted to said innovation.
- all types of development activities should be covered by SPC provided that for new formulations and indications - no SPC has already been granted for the same active principle and the first marketing authorization ever is always taken into consideration for calculating the SPC term
- It takes much more investment and time to develop a new active ingredient than to develop new derivatives or formulations.
- It is not clear whether this question is asking whether the four categories listed fall within the scope of an SPC. That is generally the case already under the current Regulation. Or whether the question is asking if active ingredients in these four categories should receive SPCs in which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- In my opinion any technological development, which requires a time consuming authorisation before it can be brought on the market, should be able to enjoy protection by SPCs. Thus, also e.g. medical devices should be eligible for SPC protection.
- SPCs are established in order to compensate entities investing in R&D for the long time needed to receive a registration of a product to access the market. - ECPA believes that any invention which is subject to a basic patent and which requires a new registration, should be eligible for SPC protection. - IN ECPA's view all products should be treated the same, independent of their nature and there should be no ranking.
- It is our understanding the current legal framework does cover for all 4 activities listed. There may be some variation in the interpretation by national authorities, but this can be solved through guidelines rather than a legislative reform.
- "new derivatives" is an unclear/broad term. When is a novel compound and when is is merelt
  a "new derivative", how much change must be made... I suppose this is the general problem
  of trying to have a simple regulation covering a complex field.
- In principle, the above developments could qualify for SPC protection, especially and mostly the development of new active ingredients. Whether or not the development of new indications and even new formulations and new derivatives can actually lead to an SPC with a positive lifetime depends on whether or not the first MA listed in the context of article 3(d) of the SPC Regulation is a truly full and independent application as meant in article 8 of Directive 2001/83, and not an MA for a line extension or variation of an earlier product. In this context we explicitly refer to paragraph 35 of COM(90)101 final. Under all circumstances we should keep in mind that SPCs have been created to make up for time lost in obtaining an MA. If no substantial time is lost, because the product is a line extension or variation, for which regulatory wise- most of the work and investment already took place for the predecessor product, there is no justification for extension of the exclusivity.
- It is already possible to obtain SPCs for each of these activities in limited circumstances where the fact-pattern justifies it. I see no need for a change.
- We have seen and agree with the comments which we understand EFPIA will be submitting in
  response to this question. Comment: It is not clear whether this question is asking whether the
  four categories listed fall within the scope of an SPC. That is generally the case already under
  the current Regulation. Or whether the question is asking if active ingredients in these four
  categories should receive SPCs in which case the answer is yes provided there is a new
  patent and a new marketing authorisation. The Neurim decision is an example of this.

- Any invention which is separately patentable and subject to a basis patent and which requires a (new) registration process should also be in principle eligible for SPC protection.
- All such 'products' should be covered in circumstances where there has been a delay in obtaining a marketing authorisation.
- New formulations to the extent that their development involved significant R&D.
- Reson is that it involves investments and development time, and it should incentivize such activities. It shall be garanteed that the system provides for a protection on the market which is strong enough, avoiding e.g. cross-label use
- A more differential approach would be desirable, as a new formulation (or indication) (such
  ach as in the case C-431/04 -MIT, where substantial clinical trials had to be carried out in
  order to secure marketing approval) may give rise to considerable medicinal benefits, worthy
  of a supplementary protection within the framework and aims of the SPC regulation. In other
  case, where the new formulation just leads to a line extension of an existing dossier such
  considerations do not apply.
- Under the provisions of Article 4 of the current Regulation, SPCs are already capable of "covering" all four of the above-mentioned categories. Thus, the question has been answered on the assumption that "covered by SPCs" should be read as "covered by SEPARATE SPCs". That is, the answer should be interpreted to mean that SPCs for derivatives, indications and formulations should be available regardless of the existence of an earlier SPC to the active ingredient per se. However, I do not believe that separate SPCs should necessarily be available for ALL such derivatives, indications and formulations. In this respect, the manner in which the question has been posed does not allow for the provision of a complete answer.
- SPCs should be granted if a separate patent exists and protects the corresponding innovation. This follows from recital 14 of the SPC Regulation for plant protection products, which allows the grant of SPCs for new derivatives of known active ingredients based on a separate patent. Neurim type SPCs are also granted on the basis of separate patents and are limited to the protected therapeutic application.
- SPCs are established in order to compensate entities investing in R&D for the long time needed to receive a registration of a product to access the market. - ECPA believes that any invention which is subject to a basic patent and which requires a new registration, should be eligible for SPC protection. - IN ECPA's view all products should be treated the same, independent of their nature and there should be no ranking.
- Any invention which is separately patentable and which has to undergo a registration process should also be in principle eligible for SPC protection.
- Neither do you require the full amount of clinical studies (you would not need a new Clinical Phase I (sometimes not even Clinical Phase II) and regulatory work for a new indication, nor for a new formulation. Often you wouldn't even need it for a new derivative.
- All these features (new active ingredients, new derivatives, new formulations, or new indications) requires substantive R&D effort. Review and approval of any of these features by EMA contribute to the regulatory delay that the SPC is designed to compensate. It is not clear whether this question is asking whether all these features fall within the scope of an SPC that is generally the case already under the current Regulation or whether this question is asking if active ingredients in all these features should receive SPCs in which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- When coming to derivatives and formulation, there could/should be a threshold where "inventive step" is required for an SPC. No obvious derivatization or change in formulation should be included, but definitively "ingenious" solutions should be promoted/praised.
- This question is not clear. "Development activities" are not covered by SPCs; products are.
  And products that may comprise a new formulation or new active ingredients or be directed
  to new indications or be categorized as new derivatives (or old compounds, I assume)
  already may be "covered" by an SPC, if the criteria for issuance of an SPC are met.
- If there is a granted patent for such developments, and the other requirements of the Regulation are met (e.g. a new marketing authorisation) they merit the grant of an SPC.

- As long as the product requires a new registration then it should covered by an SPC
- We have assumed when answering question 33 that the question relates to which developments we believe should be covered.
- This question is not clear it could mean that the SPC Regulation presently covers all of these
  activities in which case the answer must be "YES", or whether active ingredients falling into
  one of these four categories should receive SPC protection, in which case the answer must be
  "YES", if there is a new patent and a new Marketing authorisation in place (see Neurim
  decision).
- It is not clear what is meant by 'covered' in this question, nor what is intended by 'derivatives'
  which could be simple derivatives, e.g. salts, or more complex derivatives resulting in a new
  chemical or biological entity. It is, and should remain, potentially possible to obtain SPCs in
  any of these categories providing there is an appropriate, relevant patent and marketing
  authorisation.
- In my opinion there is no schematic answer. All developments can result in a substantial clinical improvement of the patients and this development can require substantial investment in R&D. This can apply even to formulations. An SPC on a formulation patent can also be acceptable, if the other criteria of the SPC Regulations are fulfilled. All requirements of Art. 3 of the current SPC Regulations need to be taken into account. Taken them all together is a rather balanced system,
- All developments that increase safety, patient compliance etc and which require substantive approvals should be rewarded.
- none
- For number 1 and 2, only if it really is something new
- The grant of a SPC should be connected to the efforts spent for this new development
- provided that the new derivatives provide a significant contribution and are not merely an optimisation, obvious to try in the Pharma field.
- prefer to keep SPC Regulation very lean. For new derivates, formulations, indicsation, protection should be managed via data protection (TRIPS)
- All developments that require new marketing authorizations and provide a substantial medical benefit should be eligible for SPC protection
- This question is completely unclear. Does it mean "Which types of patent claims/patentable subject matter should be the subject of SPCs?" or "Which development activities should be infringements of SPCs?"
- NO. We do not favor the reopening of the SPC
- SPCs should be available for the outputs of all the above development activities provided
  they result in a marketing authorization and are covered by a basic patent. Products
  embodying the above developments can be covered by the scope of an SPC. Research
  itself is of course not covered.
- All of these should be covered as they involve considerable investment, relate to medicinal
  products and so require regulatory authorisations which can take time and which can also
  give rise to new inventions and patents. If the requirements for an SPC are met, there is no
  reason to exclude any of them.
- If there is a new innovation that gave rise to a patent and a new marketing autorisation, then that should indeed lead to SPC protection. One example is described in the Neurim decision.
- With regard to formulation, the change from immediate-release to controlled release, or the change from tablet to solution should be covered
- In the 2nd checkbox the expression "new derivative" is too vague and ambiguous. If a derivative is patentable it should qualify for a separate SPC.

- The problem is not which activities are covered, but that these activities do actually entail a technological enhancement.
- New indications and in some cases derivatives recieve regulatory exclusivity
- It is not clear whether this question is asking whether the four categories listed fall within the
  scope of an SPC. That is generally the case already under the current Regulation. Or whether
  the question is asking if active ingredients in these four categories should receive SPCs in
  which case the answer is yes provided there is a new patent and a new marketing
  authorisation. The Neurim decision is an example of this.
- ...insofar as the patented, new invention provides a new clinical opportunity and leads to a new marketing authorization
- We support Efpias comments
- Threre is no justification for delays in the development of anything but new active ingredients. Only the preclinical and clinical trials for new molecules deserve the extra patent life, because they really benefit society. New derivatives, formulations or indications have enough with 20 years of protection because they can be started with the knowledge that the molecule works (i.e. with minimal uncerteinty) and therefore should not be extra rewarded. Of course if innovators are asked, they will request SPC for all, but simply this was not the idea of SPC in their origin.
- This question is unfortunately not very clear.
- n/a
- But in the case of new indications, retaining the constraint that there should only be one SPC per product (active ingredient).
- It is not clear to us whether the question is asking whether all the above activities would fall within the protective scope of an SPC if done by a third party and so infringe.(In this case our answer is yes in all cases.) Or if the question is asking whether SPCs should be available for the above activities. Again our answer here would be yes assuming an appropriate basic patent and a new marketing authorisation.
- It is not clear what this question is asking for. The current SPC regulation covers any of these situations. The predominant situation will be that the SPC is applied for a new active ingredient. However, if an active ingredient has already been developed by another company and your company finds a new derivative of such an active ingredient, then you will apply for an SPC for the patent covering the derivative of this existing active ingredient. The same is true if the active ingredient has been approved to another company and your company finds a new formulation. They you would apply the SPC on the basis of your formulation patent. I expect this is a situation which can apply to smaller companies.
- New formulations should be protected to the extent that the formulation is patentable and that patent term has been lost due to regulatory delay.
- It is not clear whether this question is asking whether the four categories listed fall within the
  scope of an SPC. That is generally the case already under the current Regulation. Or whether
  the question is asking if active ingredients in these four categories should receive SPCs in
  which case the answer is yes provided there is a new patent and a new marketing
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- The question is ambiguous as it may refer to the scope of a SPC or to the question for which type of invention a SPC should be granted.
- The SPC regime should be simple to administer if a development is worthy of separate, independent patent protection, then it should attract SPC eligibility. If the invention is a bad one the underlying patent can be challenged.

- It is not clear whether this question is asking whether the four categories listed fall within the scope of an SPC. That is generally the case already under the current Regulation or whether the question is asking if active ingredients in these four categories should receive SPCs in which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- Another poor question. What do you mean by derivatives? New formulations would be very
  difficult to deal with. New uses possibly the approach taken by the CJEU in Neuroscience just
  about works. But frankly, the value of second use patents (and therefore SPCs) in most cases
  seems limited
- In my view, the Regulation should promote the development of drugs most beneficial to the patients and society. New derivatives of a known drug may also be beneficial to the patients but would normally be more beneficial to the producer than to the patient.
- The development of new active ingredients, new formulations, new indications and new derivatives are and should be covered by SPCs. It is of fundamental importance to understand that pharmaceutical innovation, and addressing unmet clinical need, cannot be reduced black-and-white to one development option, but has to embrace all available options. In particular research into new formulations, new indications and new derivatives is of paramount importance. In particular small and medium-sized companies focus their innovation research to such step innovations. They would be seriously disadvantaged and disincentivized from pharmaceutical research, if SPCs for such innovation were not available.
- Fostering broader SPC allowances opens the door to market restrictions, evergreening and legal uncertainties
- It is not clear whether this question is asking whether the four categories listed fall within the scope of an SPC. That is generally the case already under the current Regulation. Or whether the question is asking if active ingredients in these four categories should receive SPCs in which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- It is not clear whether this question is asking whether the four categories listed fall within the scope of an SPC. That is generally the case already under the current Regulation. Or whether the question is asking if active ingredients in these four categories should receive SPCs in which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- The extension is granted for the long R&D process (preclinical R&D, Phase I-III and satelite clinical studies and regulatory timeframe). Shorter the process less exclusivity justified (any further development has less risk and starts from end of Phase I of the NCE).
- The R&D effort required to develop new formulations, new derivatives and new indications of existing active ingredients is substantially less than the R&D effort needed to develop a new active ingredient. The time required for marketing approval of a new active ingredient is substantially more that the time required for approval of new formulation, new derivatives and new indications. Therefore, there is no need to compensate patentees for the lost patent term in which they cannot market a patented product in the case of new formulations, new derivative and new indications. Finally, we feel that the extra period of market exclusivity provided by the current SPC regulation is ample compensation for the delay in marketing a patented new active ingredient.
- Any invention which is separately patentable and which requires a registration process should also be in principle eligible for SPC protection.
- Any invention which is separately patentable and which requires a registration process should also be in principle eligible for SPC protection.
- sometimes, a new derivative of an existing active ingredient can become a new active
  ingredient; from a patient or farmer's perspective, a new indication of an existing active
  ingredient or a new derivative with totally new uses can be as valuable as a new active
  ingredient itself
- It is not clear whether this question is asking whether the four categories listed fall within the scope of an SPC. That is generally the case already under the current Regulation. Or whether the question is asking if active ingredients in these four categories should receive SPCs in

- which case the answer is yes provided there is a new patent and a new marketing authorisation. The Neurim decision is an example of this.
- All developments listed above are, and all developments listed above should be covered by SPCs. Pharmaceutical innovation is directed in many directions to meet clinical need. It is not justified to discriminate between one objective of development or the other. Research into new formulations, new indications and new derivatives are an important dimension of innovative pharmaceutical research and require protection of investments relating thereto.
- Any invention which is separately patentable and subject to a basic patent and which
  requires a (new) registration process should also be in principle eligible for SPC protection.

### Q 36: What changes would <u>you</u> propose in response to insufficient investment in the development of new antibiotics?

- Extension of the SPC for antibiotics, similarly to the paediatric extension.
- New antibiotics will be restricted in use to avoid developments of resistent bacteria this is
  fundamentally not a good business model for the inventive companies developing these
  drugs. Compensation could be an "antibiotic extension" of an existing SPC for an new
  antibiotic in analogy to the present pediatric extension, but should be longer than 6 months,
  possibly up to an additional 5 years.
- Incentiving the companies. Similar to the US model (GAIN Act), eg. 10 years of Data Exclusivity.
- Grant +10 y market exclusivity for proven therapeutic leap innovations; find a mechanism to guarantee economically attractive prices & reimbursement for new antibiotics (major contemporary driver for decrease of attrativeness is massive price erosion resulting from free global competition).
- Incentive in term of patent protection and reimbursement
- Increased length of patent protection for the development of new antibiotics
- longer data protection (data exclusivity) period, such as for orphan drugs (excluding similarity provisions)
- I would incentive investment in the development of antibiotics giving them a similar regulatory legal frame as Orphan drugs
- TO protect antibiotics of natural origin
- need more incentives in this area, but not too sure which ones. Maybe rather than a patent term extensino, a market exclusivity is clearer and stronger.
- Significantly extended protection (beyond SPC terms), given new antibiotics are likely to be
  used as a "last resort" and thus have relatively small market size, at least for the immediate
  patent term. Orphan protection is unlikely to be appropriate given desire to have multiple
  new antibiotic options.
- A mixture of push and pull incentives. Notwithstanding my previous answer, I am not sure that the answer lies in changing the SPC regulation since even a prolongation of patent term/exclusivity by many years would be insufficient to make antibiotics research commercially attractive. Thus, looking at the problem, the notion of a "transferable patent/exclusivity voucher", whereby a company successfully investing in new antibiotics would get a voucher for another product, has the potential for an effective market based-incentive. In contrast to alternatives such as Market Entry Rewards who would fund the pool to raise sufficient money? what happens if the pool is depleted? the transferable voucher which could be linked with some qualifiers against abuse would not require immediate upfront signing of big checks.
- If the market for development of a new antibiotic is to small to be attractive, public research should be encouraged.
- Provide a legal definiton of "protected by" in Article 3 a)
- Longer duration of SPC
- SPC protection for antibiotics for 15 years
- Extended SPC terms specifically for new ANTIBIOTICS
- Possibly longer duration and/or possibility to obtain an SPC for new indication
- No strong opinion

- Specialized exclusivity provisions
- Extra extension of duration. For instance 16 years from approval and/or maximum of 6 years.
- Maybe similar to pediatric extensions for SPCs or the current orphan drug incentivization
- Extending the duration period of the certificate Clarifying the scope of protection for biopharmaceuticals
- There needs to be an additional compensation for developers of antibiotics, which should be
  used minimally from a medical point of view, after marketing authorization was obtained; an
  antibiotic extension of an SPC could be a solution, similarly to the pediatric extension, which
  could be taken away or lapse after a certain period of time, when the antibiotic is
  recommended by the medical society or marketing authorization agency for broader use.

## Q 38: What changes would <u>you</u> propose in response to insufficient investment in the development of some categories of orphan drugs?

- Allow more SPC time for orphan drugs compared to potential blockbusters to allow recouping investments
- It depends e.g. if the drug was already approved and under which conditions (e.g. formulation, dosage, etc...) since cross-label use may happen in some situations and thus the protection is diluted The status of orphan drug is to my knowledge also revisited which gives uncertainty to an investment
- Explicitly cover toe conditional marketing authorization, which is generally obtained by EMA for orphan drugs.
- I would favour at least clarification on when orphan drug exclusivity can extend to similar APIs. Here, there is litigation and we need, above all, a clear and predictable situation.
- As with pediatric indications the SPC could be extended if the approval is for orphan drugs.
- none
- longer SPC term
- Prolong SPC protection from 5 to 15 years in order to enable companies to recuperate their investment.
- longer duration of protection for certain categories of orphan drugs but at the same time changing the way in which marketing authorisations for such indications are granted to allow entry of generics once the protection is expired. In the current situation orphan and non-orphan indications can coexist under the same marketing authorisation, making difficult for generics to enter into the market once the protection for one of the indications expires. Also, the question of similarity of orphan drugs should be reviewed since it can lead to situations where new indications or formulations for an orphan drug may block the entry of generics of other similar products or old versions of the same product.
- Extended SPC terms
- In addition to the extention of duration of the exclusive it could be devised a system of detaxation for activities of research specifically addressed to such purpose.
- Additional exclusivity for the "true" orphan drugs, note that some of the (former) orphan drugs are sold on a blockbuster level
- Again, as for antibiotics extra duration. 16 years from approval and/or maximum of 6 years.
- Perhaps similar to pediatric extensions
- a longer duration of the SPC (c.f. paediatric extension)

 Extending the duration period of the certificate - Clarifying the scope of protection for biopharmaceuticals

### Q 41: To which types of products would you favour extending the current SPC protection?

- To any present or future innovative products, which are on the "borderline" of falling under the
  present SPC Regulations, or which are not covered by the present SPC Regulations at all, but
  which suffer from loss of effective patent protection due to nationally required certification or
  authorisation procedures. A new, additional SPC Regulation should be flexible and should in
  particular provide adequate protection to any biopharmaceutical technology.
- Any product which requires authorisation prior to market entry
- wherever the marketing of a product requires state/EU authorisation and deprives the patentee of patent time
- In the context of the Plant protection regulation, products that are the results of other technologies such as RNAi, genome editing, new traits, etcetera should be considered
- drug delivery systems
- Any products which incur significant regulatory delay, e.g. aircraft engines, etc
- All types of products for which a specific "authorisation before marketing" is required
- all types of products for which a specific "authorisation before marketing" is required
- Medical devices only in combination with a drug

## Q 42: Please comment on the pros and cons of extending SPC protection to other fields of technology, such as medical devices, cosmetic products, or food products and food additives (both for humans and animals)?

- The development work required by some of our members in relation to medical devices is extensive and the development timescales are similarly significant so the rationale for these products to be eligible for SPC protection is compelling but BIA believe that such proposals should be covered in separate regulations. Expert input for other sectors would be required to comment on those.
- If these industries face substantial development timelines and delays between patent applications and marketing authorisation, such that investments in these technologies could be insufficient, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- the time period for a CE mark of a MD is not so Long as for a MA for a drug therefore no SPC for MD
- Pros better recoup of the investment increasing the incentives for new research Conslonger monopoly of the originator; discouraging generics; more expensive products
- Approval procedures für cosmetic products, food products and food additives (both for humans and animals) are less time and money consuming and should not be rewarded with SPC protection. However, a majority of our group is in favour of extending SPC protection to medical devices. which have to undergo a lengthy approval procedure.
- Medical device are more and more sophisticated, their development may request long investment, which may justify the grant of the SPC. The duration of the SPC may be shorter than one for a drug.
- Pros Additional research jobs in these fields of technology may be created in the EU More innovative products will be available - For medical devices, the EU will become a more

attractive market in comparison to the US and Japan, where a patent term extension for medical devices is already available. Cons - It will take longer until substitute products are available on the EU market - Prices of the products in the respective fields of technology may go up

- I refer to my earlier comment: the SPC regulation should in fact be abolished and replaced by a PTE system
- The development of food products and food additives, cosmetic products do not require long, costly research compared to pharmaceutical and plant prtection products. The definition in Art 3b listing of directives for grant of the MA seems to be exhaustive. The marketing authorisations granted according to Directive 90/385/CEE (for implantable medicinal devices). and Directive 93/42 (related to medical devices) cannot be eligible for the purposes of Regulation 1768/92
- If these industries face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- The regulatory time lines and efforts in those technologies are substantially less, than for those a SPC is currently granted
- Pro: equity Con: politicall probably difficult
- The combination of fileds put hereforth is rather big and so what I would like to take a chance to comment on are food products and additives (both for animals and humans). As I see the case, a SPC for such a field would further strengtzen a market that already is playing around ith availability of food and necessary or unnecessary supüplements to food. The first of these ecouraging, that although there is a lot of food, millions of people are dying from starvation. I think this might be even more if fodd prodcuts are not only able to be patented but also to be further protected up to another 5 yrs by an SPC. The second, which is the supplementation or additives to food, plays with fears of humans and also farmers with their animals in always proposing what is best (Which basically is not always the case). SPC on such things might further strengthen this play with fear and making money with it. But also to be considered is that even with this positive things could be achieved if research is driven in a directive to strengthen plants against extrem climate conditions making food available in different climate zones mor easy. But the main question always should be, as to who and why someone applies to a SPC and where. No benefit can be reached by stopping open research due to a SPC and the chance to further use a patent as protection of knowledge against research and further advance.
- The development of medical devices meets all or most conditions mentioned in the preamble of Regulation 469/2009 and therefore should benefit from the same protection.
- For Food products, Food additives and cosmetic products the regulatory requirements are significant lower. The time to market is nearly the same as for other products under patent like Smartphones or flat Screens, therefore patent term Extension is not needed as incentive. The term medical devices is unclear.
- The purpose of SPCs is to compensate for the lengthy development process and the time needed to undergo the regulatory approval procedures. If other industries are facing similar requirements and lose part of the effective patent protection period, we believe they should be equally entitled to a compensation in the same way pharmaceuticals are.
- All of these products are much easier, quicker and cheaper to have approved thus no SPC.
   It is much too complex a system for these products of lesser importance for society (medical devices being borderline here).
- no need for additional protection as those are not that expensive to develop, there are already sufficient incentives and protections available for those categories
- It depends on whether the product requires extensive regulatory approval and thus leads to loss of commercialisation of the product. That always has been the rationale behind setting pharmaceutical products apart from other technological developments. If we loose track of this, e.g. car manufacturers would surely also welcome a maximum of 5 years longer exclusive rights for their innovations that may also take a long time and investment before the can be brought to the market.

- Pros: Incentive to develop new innovative products especially those that may involve lengthy/complex development. Cons: Very difficult to draft any new Regulation that will capture all of these aspects and advances any better than the current Regulation. I would prefer to maintain the current Regulation as is for certainty.
- It does not make sense to include product categories other than medicinal products, because these do not undergo such a long approval process.
- If these industries face substantial development timelines and delays between filing a patent application and obtaining marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks and commercial conditions, separate regulations would be the best way forward.
- In a certain way the SPC Regulations represent a prolongation of the terms of a patent, for very well known reasons (time gap to receive the marketing authorization). Those reasons do not apply sufficiently to the other fields of technology as mentioned in the question. Even if possible difficulties in defining the border between - for example - medicinal products and medical devices would the be relieved the more or less the same problems would arise at another point.
- If at all, it should be taken into account that every industry operates according to different rules, especially regarding marketing authorizations. Therefore specific legislation would be needed. It should be done in separate regulations.
- SPC protection should be available in circumstances where a product covered by a patent suffers from delay in getting to marketing as a result of need to get statutory approval.
- If at all, this should be covered in separate regulations.
- Con: there is no need to foster these filelds or set up (new) incentives, 20 years of patent protection is fair and sufficient
- Pros for medical devices is incentivize this area of R&D which involves also high costs and risks Cons for cosmetics and food additives and products is that they do not undergo highly
  regulated very expensive and long development stages
- pros: more research / cons: not always ethical especially on food products and food additives
- If the level of regulatory scrutiny (and as uch delay in approval) would be equivalent to that required for a medicinal drug, such products would be classified as such, so there does not appear to be any need to extend the SPC sytem
- As the SPC system is aimed to compensate delays in Regulatory processes, other technical
  fields where a strong regulatory process exists before entering the market should benefit of
  some compensation in the lifetime of the patent
- With the current regulation, this would severely handicap small companies that do not have the necessary funds to apply for this type of protection.
- Extending the protection to these other mentioned fields of technology would go against the spirit of the SPC regulation and does not seem justified.
- SPC is compensation for the long authorization process. As there isn't such a long authorisation process at the other products they do not need SPC.
- The regulatory approval period for these products is short, not delaying the launch of the product and return of investment. Development costs are lower, no significant burden of clinical trials
- Medical device regulation recently changed in 2017 and it is clear that longer development times and more clinical data is required to develop new innovative medical devices. The development time lines will extend eating into the patent period
- to promote innovation in targeted areas (innovative devices, food additives having provide data)

- Compared to human medicinal products, the fields of technology mentioned above (medical devices, cosmetic products, or food products and food additives) differ with respect to at least: market conditions; technical requirements to obtain market access; financial investment required to develop and market products; and existing incentives to develop and market products. Therefore, if SPC-like protection is to be extended to any one or more of those fields of technology, it would only be appropriate to do this by way of legislation that is completely separate from the Medicinal Product Regulation and that contains "unique" provisions governing eligibility, validity and/or term (to reflect the above-mentioned differences).
- pros: profit increase for big companies cons: supports monoply, greater prices of protected products, less jobs, transfer activities in non-SPC countries
- Extension of SPC protection to medical devices may be considered if time consuming authorization procedures corresponding to directive 2001/83 are required in order to be able to place the product on the market. Since the other products do not require lengthy authorization procedures, we fail to see the need for SPC protection.
- The main aim of spc regulation was to compensate the time of the compulsory lengthy testing
  and clinical trials that pharmaceutical products require prior to obtaining regulatory
  marketing approval. In my opinion, cosmetic products, food additives and medical devices
  have a more straightforward regulatory procedure and therefore these products do not
  require a compensation through an SPC.
- Compensation of reduced patent term due to lengthy registration processes might be relevant for other fields of technology SPC protection should generally be open to and take new technologies into account.
- Thre is no legal basis as for the drug development. No comparable regulatory effort is necessary before the lunch of such a product.
- As all technical advantages can easily be protected by patents, and teh regulatory work is
  not as demanding as it is in the pharmaceutical business, there is no necessity to make things
  as complicated as they are for pharmaceuticals now. One could however think about an
  exclusivity right (like the data/market exclusivity) to protect the Investment in research and
  development of those medical devices which brought a specific combination of diagnostic
  or therapeutic effect together with a specific technical solution to the market first. The SPC
  Regulation and how it is interpreted is a can of worms that no other industry could wish for.
- The pros are that for many, if not all, such fields of technology the companies making the research investment and then marketing the results of their research also have to obtain an "authorization" to market those results, even if the authorizations are governed by laws (directives, regulations, etc.) other than the regulations identified in art. 3 of the two current SPC regulations. So they too should benefit from the sui generis extension of the patent protection in the event that obtaining such "authorization" takes e.g. more than 5 years from the filing date of the corresponding basic patent. The cons are that it may be difficult to determine whether the duration of the new SPCs to be granted for such other fields of technology should be calculated in the same way as now provided by the two current SPC regulations (the difficulty may lie in making an economic determination of what that duration should be, rather than in making the corresponding calculation once the duration has been established by law). In general, for ALL SPCs regardless of the field of technology I would favour a duration corresponding exactly to the amount of time lapsed between the filing date of the basic patent and the notification of the authorization, rather than the current system where a number of years (now 5) is subtracted from that amount of time. The reason for this is that in all other fields of technology where no authorization is required in order to market the subject-matter of a patent the patent owner enjoys 20 years of monopoly (i.e. the entire duration of the patent), while with the current system the duration of the monopoly for pharmaceuticals and plant protection products is 15 years. This makes no sense to me.
- Since we do not develop and make any of these products, we cannot comment on whether
  any SPC protection would be needed or otherwise meaningful. Under the proviso that these
  industries also face substantial development timelines and delays between patent
  application filings and receipt of marketing authorisation, the concept of SPC protection may
  be applicable subject to separate and independent regulatory framework and legislation.

- Extending SPC protection to other fields of technology would encourage even more sophisticated research and could result in higher degrees of safety as regards the final consumer.
- Pro: encouraging development of products which improve life quality.
- To the extent the purpoe of the SPC regulation applies to these other technologies that is
  they involve lengthy and expensive development times prior to and in order to obtain
  marketing authorization and thus suffer loss of patent term, extension of SPCs may be
  appropriate. However, these should be SEPARATE regulations tailored to the particular
  circumstances of those products.
- I believe regulatory requirements would be more sufficient than SPC extension protection.
- TO be taken in the account the time to market and the life cycle of the specific product; if
  the time to market is relatively long, off course we will be in favor. Otherwise, extending SPC
  regulation independently from the above, would dramatically change the rationale of the
  SPC regulation.
- Be more strict and more aware of the medical products, device or even the additives we
  ingest and use
- I have no objection but this should be subject to separate Regulations for these areas and not achieved by unnecessarily amending the Pharma Regulation
- in line with other countries as the US, and medical devices are very similar to pharma products. Against extension to other categories.
- There is no reason to discriminate between technologies when it comes to compensating
  "market time lost" due to regulatory review. The underlying idea is to promote innovation and
  that the public gets access to the latest technologie and when innovation is shifting to other
  technologies (which are then also regulated) then the SPC system is ideally equipped to
  stimulate those other technologies as well.
- Where these industries faced substantial development timelines and delay between the filing of patent applications and obtained Marketing authorisations, e.g. due to studies necessary for guaranteeing safety of human beings or animals or proof of efficacy of the product, the concept of an SPC protection might be applicable. In this case, specific legislations would be necessary for these different industries as all of them underly different regulatory Framework, like presently the case for pharmaceutical products and plant products which have different SPC regulations.
- no comment
- We recognise that other areas of technology such as those noted in the question may currently be subject to patent term erosion due to lengthy regulatory requirements and agree that in such cases a period of supplementary protection would be appropriate. However, in view of the varying requirements across these sectors and different regulatory pathways, this aim would need to be achieved by completely separate and distinct regulations. A single regulation to cover all sectors would be far too complex.
- The lifecycle in the fields looks short. The extended SPC may not be necessary for the product whose lifecycle is short.
- 20 years patent protection is sufficient. It has been seen in these past years that teh SPC regulation has just opened doors for abuse and evergreening. There is a lot of litigation in this field and despite this, the situation remains totally unclear and unpredictable. This situation should not be extended to other fields as it is unsatisfactory.
- I don't see a substantial reason to extend the SPC system to cosmetic products and food
  products/additives, since balancing of the interests of all stakeholders do not support that:
  here is no outraging public interest in investments into cosmetics or food products/additives
  which goes beyond the ordinary patent system.
- It is questionable whether it would have any impact to in the Regulations current form to extend to food products since the time to market is usually not very long

- Although these other fields of technology have regulatory frameworks, like pharmaceuticals
  and plant protection products, they are of a different form and scale. The nature of such
  frameworks and economic cost/benefit would have to be considered carefully before
  extending SPC protection to such fields.
- Medical devices should be suffently tested for safety and efficacy, and this investment should be awarded
- The development and approval procedures for these listed products are not so long i.e. less than 5 years so even if in theory they could get SPC protection no SPC would be granted. Consequently it is pointless to extend the SPC protection to them.
- I oppose to extend the SPC protection to other fields. These products do ot need 10 yrs of development time to come into the market. Other technical products need marketing athorisation, too. They are also blocked from market entry without this marekt approval.
- From the perspective of small companies and mainly generic pharmaceutical companies, such an extension would mostly be in favor of larger multinational companies. Further more, pharmaceuticals is a more directly health related/oriented industry and extending the protection would open up to same protection to certain products that don't have the same purpose.
- Contra: The benefit for society is smaller as compared with medicines, and the regulatory requirements are lower, too
- SPCs are already granted permissively in the field of pharmaceuticals, which generates undue monopolies affecting access to medicines and weighting on public health systems in Europe. The first priority should be to fix these problems and to assess whether SPCs are really incentives to favor R&D or mostly generating financial constraints upon members States.
- Justification for SPCs (time for regulatory approval) does not apply to the same extent, investment in medical devices, cosmetic products etc is normally not as high as in pharmaceuticals, pharmaceuticals are more important than cosmetic or food products (SPC might be suitable for medical devices, I lack knowledge of investment in this field).
- cons; not fair to extend protection on products that do not require the investment in time end money as do pharmaceuticals
- Cons: these other fields of technology do not have the same costly and lengthy process for getting a Marketing Authorisation . No SPC protection for compensating for their development should be necessary.
- cons: the purpose and constrains for the medical devices, cosmetic products, or food products and food additives (both for humans and animals) are different pros: unique administration, like FDA
- For cosmetic products, there is no need of clinical testing during several years (as drugs)
- It is unclear how extending protection in those other fields of technology is related to the compensation for the time period reuired to obtain a marketing auhorization, which is the ground behind the SPC
- Time to market is much shorter for medical devices, cosmetic products or food products than for new molecules.
- SPCs shall depend on what requirements set on registration for marketing. It would vary consdierably between the mentioned fields and raise difficulties in assessing reasonable term scopes.
- Unless there is a substantial regulatory burden to bear before marketing access, I see no reason to provide an SPC for these products. Implantable medical devices may be an exception to this.
- We do not favor at all the reopening of the SPC protection. Any attempt to extend it may weaken the current one.
- Our members work in a wide range of technologies. Any area of technology that faces significant regulatory delay should be permitted to receive an SPC. This would best be done

by separate regulations which take into account the interests in these different technological areas rather than by amending the existing SPC Regulations.

- Considering medical devices, there have been a number of contrasting decisions in Europe, including those where SPCs have been granted for medical devices. These decisions explain why medical devices SPCs are merited and the pros i.e. to adequately compensate and incentivise medical device companies for all of the reasons in parallel to why there are SPCs for medicinal products, including as they require considerable investment, suffer regulatory delays and give rise to inventions and patents. I think a separate system should be implemented (indeed as there is already for plant protection and medicinal products). It might be said that con would be that, unlike medicinal products per se, there is likley a need to decide whether all or only certain categories of device should qualify for protection. This would not be so much of a con, and would more appropriately be an issue to be negotiated with the industry eg considering estblished and clear categories of device such as Class III devices and/or drug+device combinations.
- If there are other industries where there are significant development and approval timelines
  that create a delay between patent filing and launch, then I would favor an SPC like regime
  for those industries.
- Increasing regulation, (e.g. the EFSA register of health claims, new medical devices regulations) means that companies are having to commit increasing proportions of funds to research and systems development. This additional work and investment deserves to have protection.
- We believe it is not important to extent SPC protection to the fields mentioned above because these product categories have shorter development timelines and often other approval procedures (i.e. medical devices - TÜV approval).
- We don't see relevant pros.
- Pros additional value in development Cons- higher prices, some of these technologies have a short time to market
- see case C 431/04, this is an area where SPC reward may well be worth while
- If industries operating in these fields face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- Substantial investment into medical devices would be protected. The dividing line between pharmaceuticals and medical devices is becoming less clear, and much work has to go into putting a new medical device on the market.
- If these industries face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- Cosmetics and food product fall under much less strict regulatory requirements, the different durations of SPCs would complicate the system
- We support Efpias comments
- In our field, food and cosmetic additive may have an impact on human health. In addition, the resources in time and economic invested for its investigation.
- Unlike for drugs, there is in general no justification in terms of delay of entrance in the market.
- Monopolies are bad. There is no need to give more room to the CJEU.
- the time to develop and get approval for these products would deserve an adequat protection in view to encourage their development
- Not relevant to pharmaceutical industry.
- Difficult to answer as I don't fully understand these industries. But I don't think development timeliness are as long in such industries as in Pharma Industry. Furthermore, the launch of a

copy (after the patent expiry) in such Industries does also not result in the same dramatic drop in prices and volumes as faced in Pharma Industry. Indeed, in the Pharma sector, the Public Healthcare authorities do actively promote the market entry of generic (off-patent) products/copies, and do ensure a strong price drop takes place after the original product patent expiry. Public Healthcare authorities do stimulate fast and strong generic competition by incentive policies e.g. oblige pharmacies to substitute the prescribed drug with the cheapest product. In the cosmetic/food industry there is no Public Health Authorities actively pushing for strong price drop and neither are the Public Health Authorities actively stimulating generic competition (e.g. obligation to substitute with the cheapest product). In Cosmetic Industry, the banding is probably more important and I have never been shown that after a patent loss such companies face a e.g. 60% price drop and a 80% volume drop (after years such companies built brant loyalty). We cannot compare these Industries as Pharma Industry is fully dependent on Public Authorities and Payers and because Public Authorities and Payers actively impact the market by actively promoting generic competition and price drops.

- Reduce cost for increased competition
- Modern high-tech medical devices, implants etc. have similar development efforts and times
  as classical drugs, thus an SPC protection would be justified. In some cases the border
  between "active ingredient" and "medical device" (e.g. therapeutic microchip) may also be
  blurred.
- if there is substantial effort and money invested these fields of technology should be accessible to SPC
- As these industries face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable
- We do not favour amending the current SPC Regulations to cover new fields of technologies.
  We think they should obtain SPC protection via new Regulations that take into account the
  various interests in those technology fields. One important factor will be the period of
  regulatory delay that occurs with such technologies which may be different to the delay
  faced by pharmaceuticals and veterinary products.
- Patents comprising food products and food additives are often let to lapse before the expiry
  of the 20 years: no need for SPCs. The same applies to cosmetic products. However, SPC
  protection could be extended to medical devices.
- Extension of patent rights generally cements positions of incumbents, but it is not proven that pharmaceutical advances are made by these incumbents.
- If these other fields of technology require lengthy development timelines and their approval is regulated, such that effective patent term is lost, then a separate SPC legislation for these industries/fields of technology may also be appropriate.
- in general, only intensive development and long regulatory procedures should be awarded
  with an extension of protection, but this is not the case for cosmetic products, food products,
  in some cases it is true for food additives
- Pros: Where regulatory delay causes a loss of effective patent protection, it makes sense to compensate an applicant. Otherwise, there is a risk of discouraging research into products that are subject to regulatory delay. For example, class III medical devices can be subject to substantial regulatory delay, but do not typically receive compensation with an SPC. The UK Patent Office (Hearing Officer Decision Leibniz BL O/328/14) and German Federal Court (case 14 W (pat) 45/12) both refused an SPC for Leibniz's Nanotherm® device (a medical device for treating brain tumours) despite 17 years of delay from the patent filing date to first marketing authorisation (including 11 years of pre-clinical and clinical trials). The German Federal Patent Court even acknowledged that the effective patent protection for medical devices is insufficient for recovering the investment put into research owing to the necessary preclinical and clinical studies and the authorisation procedure. Cons: Amending the current SPC Regulations to cover other fields of technology could lead to additional complications in SPC law. Instead, we suggest the introduction of new stand-alone rights, which can take in account the specific needs of other fields of technology. For example, a new SPC for medical devices, separate from the current SPC Regulations for medicinal products.
- If these industries face substantial development timelines and delays between patent applications and marketing authorization, the concept of SPC protection may be applicable.

As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.

- If these industries face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- Regulatory requirements for medicial devices are now sufficiently onerous that they delay time to market and so justify SPC extensions to patents protecting these products.
- If these industries face substantial development timelines and delays between patent
  applications and marketing authorisation, the concept of SPC protection may be applicable.
  As every industry operates according to different regulatory frameworks, specific legislations
  would be needed for these, as is the case for crop protection products
- Key is the regulatory process if it resembles original Dir 65/65 and there is a considerable amount of time spent carrying our development to get product to market, thus limiting effective term, then seems just.
- The SPC regulation is directed to drugs/plant protection products where tests and approvals are needed in order to place the product on the market. The extra benefic (prolongation of the protective period) is in my view justified due to the common interest in society in developing new medicinal drugs and protecting crops. Medicinal devices, cosmetic products and food additives are "nice to have" nut not "need to have" and therefore, the protection offered by the patent itself should, in my view, suffice
- The SPC Regulations for pharmaceuticals and plant protection products were conceived to
  encourage and foster research in specifically regulated industries, in view of the impact of the
  regulatory framework on product development timelines and thus the exploitation of patent
  protection. The other technologies are subject to a different legal framework. Extending SPC
  protection to other fields of technology would jeopardize the cohesiveness of the existing
  legal framework.
- SPC is based on high investment and longer development time of NCEs
- If these industries face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- for medical devices, research for obtaining authorisation is also quite long
- Medical device/drug combinations may presently be excluded from SPC protection even if
  the drug is an innovative development. This is unfair and discourages pharmaceutical
  research in that field. It should be noted that device/drug combinations are evaluated by
  authorities such as EMA in the so-called consulation process and that the drug component is
  subject to a level of scientific scrutinity regarding therapeutic efficacy and safety that is
  equivalent to conventinal drugs.
- If these industries face substantial development timelines and delays between patent
  applications and marketing authorisation, the concept of SPC protection may be applicable.
  As every industry operates according to different regulatory frameworks, specific legislations
  would be needed for these, as is the case for crop protection products.
- Encouragement to commit the necessary investment in developing products where safety studies are required (where they are necessary to bring a product to market), in particular medical devices, especially combination products involving devices having pharmaceutical actives, for example. The same principle would apply to food additives.
- As it was mentioned earlier extension of monopoly is because of long period of R&D (10-15 years). These fields of technology needs significantly less duration for R&D activity.
- There is no justification to extend SPC protection to medical devices, cosmetic product or food products, as these fields to not require lengthy approval processes (unlike in the pharmaceutical field). In the case of medical devices, assessment of possible SPCs may be conducted on a case by case basis (e.g. medicated medical devices that require a pharmaceutical marketing authorisation).

- Compensation of reduced patent term due to lengthy registration processes. SPC regulation should be generally taken new technologies into account.
- In principle, SPCs should be available to any industry which faces regulatory delays in placing
  its product on the market. This should be achieved by ways of separate regulations in order to
  balance all interests in the relevant technological area. It would not be appropriate to
  reopen the current human/veterinary and crop regulations to achieve this aim.
  Compensation of reduced patent term due to lengthy registration processes. SPC regulation
  should generally be taking new technologies into account.
- SPCs should be available for products in technical fields where lifecycle of products is usually longer than the patent term, and patent protection is a relevant factor for successful competition in the market; additionally, only products where there are substantial delays due to regulatory requirements before they can be brought to market, should benefit from SPC-protection; having in mind that in the US it is possible and usual to obtain Patent Term Extensions for class III medical devices, it appears that a corresponding possibility should also be available in EU
- I am concerned that any extension of SPC protection to areas other than medical devices would lead to spurious applications being made for SPCs
- There is no evidence of advantages to society of extended SPCs and there is evidence of the negative effect of the proliferation of exclusivity rights in the filed of pharmaceuticals including SPCs. Market exclusivity leads to monopoly pricing and this increasingly has a negative effect on health budgets. This may be less relevant for cosmetics but one would want to expand SPCs to other areas of essential goods such as medical devices or food.
- If these industries face substantial development timelines and delays between patent applications and marketing authorisation, the concept of SPC protection may be applicable. As every industry operates according to different regulatory frameworks, specific legislations would be needed for these, as is the case for crop protection products.
- If these product categories face substantial development timelines and delays between
  patent applications and marketing authorisation, the concept of SPC protection may be
  applicable.
- Pharmaceuticals and plant protection are developed within the confines of a specific regulatory system, which significantly curtails the exploitation of patent protection. Other technologies governed by different legislation, which is not comparable. Extending SPC protection to other fields of technology would compare apples to oranges, and, in turn, risk undermining the coherence of the regulation devised for pharmaceuticals and plant protection products. Furthermore, the different role of patent protection has to be taken into account. Product lifecycles in other technologies are completely different, leading to a different relative relevance of patent protection. Should empirical evidence demonstrate that patent term is a relevant driver for product development in those technologies, and that, due to delays in time to market caused by a regulatory environment, investments into innovation research may falter, unless the delay is compensated, separate and taylored regulations should be considered, instead of extending SPC protection (under the current system) to other technologies.
- If at all, it should be taken into account that every industry operates according to different rules, especially regarding marketing authorizations. Therefore specific legislation would be needed. It should be done in separate regulations.

Q 43: Regulation 469/2009/EC does not define the concept of "active ingredient". All in all, would you favour or oppose including a definition of "active ingredient" in Regulation 469/2009/EC?

- additional comments -
- The current case law has taken 30 years to develop and has established a reasonably clear understanding of what the "active ingredient" is. If attempts were made to compress this case law into a short definition in the legislation, it would inevitably create new uncertainties and raise additional questions for the courts, which would be extremely counterproductive.

- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- To increase legal certainty
- As mentioned above, an amendment of the present Regulation 469/2009/EC, including an
  extended definition of the term "active ingredient" is not favorable. Instead, there is a need
  for a new, additional SPC Regulation.
- There is not sufficient reason to further define "active ingredient" as the CJEU has provided clarity to this term. Any change in definition may increase legal uncertainty not increase certainty.
- The definition of the active ingredient is not helpful. SPCs should not be granted for a
  subsequent product with the same API. This is not clear in the regulation and also not clear in
  the case law. Linking the API to the approved indications by such a definition would
  wrongly suggest that a new indication can be a subject to another SPC without fulfilling any
  specific requirements.
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- It must be an appropriate one and not exclude new SPCs for innovative formulations of the same active ingredient
- A definition is already included in Regulation EC n. 1610/96 for the agrochemical sector. If
  the case law of the CJEU should be taken into account (e.g. case C-11/13), the following
  slight amendment is suggested: Art. 1.3 of EC n. 1610/96: Active substances: Substances or
  micro-organisms including viruses, having general or specific action of its own... or plants,
  plant parts or plant products (e.g. toxic, phytotoxic or plant protection action).
- The concept of "active ingredient" can be easily interpreted by the CJEU case-law. We do not see a need for including a definition in the SPC Regulation.
- Yes, the CJEU is not being clear, so the legislation should be
- I believe that the current caselaw now provides a reasonable degree of certainty. Any new definition is only likely to result in further CJEU references.
- Clear distinction between pharmacologically active & other active ingredients (e.g., enhancers, stabilizers) should be made.
- 'Active ingredient' is not a significant problem now; it has largely been clarified by case law, and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to allow the case law to evolve organically, if and as needed.
- This is a very critical issue in the SPC system; the concept should be defined but only by
  experts in the formulation of legal texts with a high knowledge of the existing problems.
- A definition of "active ingredient" is already included in regulation EC 1610/96 for the agrochemical sector. Definition of an "active ingredient" has been clarified by case law by the CJEU, e.g. see C-11/13, where an active ingredient has been defined. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- Any new definition would necessarily raise many questions for interpretation by the CJEU and
  it is therefore preferred to leave the case law evolve organically, if and as needed.
- The current case law has established a reasonably clear understanding of what the "active
  ingredient" is. If it would be attempted to compress this case law into a short definition in the
  legislation, it will inevitably create new unclarities and uncertainties and raise additional
  questions for the courts, which would be extremely counterproductive.

- Has created quite a lot of uncertainty so far
- This is difficult, in the absence of a concrete proposal. The may referrals to the CJEU howerver seem to suggest that there may be room for improvement
- Definition is given in other legislature, e.g. 2001/83/EC
- Some vaguesness allows jurisprudence to develop to keep up with technological developments. If you define it it is constrained.
- Starting with the MIT decision, the CJEU's case law has clarified that the term "active ingredient" only encompasses ingredients "which produce a pharmacological, immunological or metabolic action of their own". Whilst it is perhaps questionable whether this produces a "fair" result in respect of certain other ingredients (e.g. novel adjuvants), it at least draws a clear dividing line with regard to eligibility for SPC protection. However, there is no doubt that the current situation is imperfect. Firstly, the CJEU appears to have failed to consider that some ingredients that are treated by regulatory authorities as being "active" (e.g. diagnostic agents or inhibitors of the metabolism of other actives) do not appear to fit the definition of "active ingredient" in the MIT decision. Secondly, a requirement seemingly introduced by the Forsgren decision (for the action of the active ingredient to be "covered by the therapeutic indications of the marketing authorisation") is highly problematic in it: (1) appears to have no solid basis in the legislation; (2) conflicts with the CJEU's prior case law (e.g. Yissum, where the court found that a medical use "does not form an integral part of the definition of the product"); and (3) poses highly complex, technical questions that run contrary to the objective for the SPC legislation to provide "a simple, transparent system which can easily be applied by the parties concerned" (see paragraph 16 of the Memorandum). Nevertheless, it is clear that these problems are of the CJEU's own making, and do not derive from the absence of a definition of "active ingredient". In this respect, it is doubtful whether addition of a definition of "active ingredient" would lead to any (more efficient) resolution of those problems. Further, the new definition would itself require interpretation by the CJEU, which would be liable to increase uncertainty (and disharmony, in the period prior to definitive CJEU rulings on the new definition).
- Meaning of "active ingredient" has been clarified by CJEU in GSK C-210/13. Difficult to say
  whether further clarification would be helpful.
- A definition is already included in Regulation EC n. 1610/96 for the agrochemical sector. If
  the case law of the CJEU should be taken into account (e.g. case C-11/13), the following
  slight amendment is suggested: Art. 1.3 of EC n. 1610/96: Active substances: Substances or
  micro-organisms including viruses, having general or specific action of its own... on plants,
  plant parts or plant products (e.g. toxic, phytotoxic or plant protection action).
- Definition of an active ingredient has been clarified by case law, e.g. see C-11/13 where an active ingredient has been defined as having an active effect of its own. The definition as given in Question No 44 includes a functional definition, which is sufficient. However, the definition should not be restricted to the registration directive as this does not sufficiently seem to take new developments into account.
- It would be difficult to not find new loopholes and uncertainities in a definition...
- The definition should be perfectly aligned with the one currently contained in other EU
  legislative instruments such as the Code of medicinal products.
- The definition of "active ingredient" is not a significant problem now, it has largely been clarified by case law and amending the Regulation now to include a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- There is not significant uncertainty with respect to the definition of this term and permitting case law to develop around the definition to the degree uncertainty does arise (for example, in the case of new technologies and new scientific learnings) makes much more sense than amending regulations every time a little uncertainty arises. Furthermore, adding more words usually creates more uncertainty, not less. Thus, trying to insert definitions into existing regulations will only increase referral to the CJEU not decrease it, as the new words will no need to be interpreted.

- A definition should be carefully considered in terms of many open issues ie biopharmaceuticals or derivatives of the therapeutic molecule, in view of the basic patent.
- This issue has been addressed by the CJEU and is now largely settled law. Any attempt to introduce a definition would merely create more uncertainty and additional litigation.
- For Plant protection the definition is already included in the regulation
- We think this is sufficiently clarified in caselaw.
- In our view the term 'active ingredient' does not currently cause significant difficulties. However, if a new definition were introduced this would very likely raise new issues of interpretation.
- I think that a definition of "product" should be reconsidered rather than a definition of "active ingredient".
- the case law of the CJEU is clear on the question what is the active ingredient. If the SPC Regulation clarifies that also a formulation or drug delivery system with an active ingredient is eligible for SPC protection there is no need to newly define the active ingredient. If a new definition of the active ingredient would be linked to the regulatory law, this would mean to leave the SPC system as a sui generis system. Both systems the SPC system and the regulatory laws do not serve the same purpose; hence the two systems should not be formally linked together.
- I think the legislation should not be too specific since the World changes and we cannot foresee how and in what direction. Having specific definitions in a very no-agile system would not be og benefit to anyone
- the definition of "active ingredient" does not appear to be an issue. It should be the active ingredient identified in the marketing authorization.
- Unnecessary as this concept has only been difficult in a small minority of cases and the courts have been able to resolve the issues sensibly to date.
- for legal certainty
- Combinations of active ingredients and of active ingredients with enhancers should be contemplated.
- Regulation should be clearer on the definition of active ingredient to reduce legal
  uncertainty, it should be clearly defined if active ingredient includes combinations of different
  INN or combinations of INN plus certain types of excipients which would confer different
  activity to the molecule
- The likelihood of the legislator getting it right, in view of future developments, is small. It may be better to leave it to the POs and CJEU to interpret in view of such developments
- The concept of active ingredient is not controversial. Any new definition would raise more legal questions than it answers.
- It is hard to see how any definition would not also be contested and give rise to the disputes seen in the existing caselaw.
- This term has been clarified by the case law of the EUCJ. Even if a newe definition would be included in the Regulation, it would raise new questions, uncertainties and referrals to the EUCJ, which would not help.
- This should be subject to jurisprudence and additional case law should regulate this and provide the necessary guidance!
- Very much in favor of definition, but getting the right definition can be tricky
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.

- In an ideal world, I would favour such a definition, but given the EU lawmakers' track record in this arena, I consider it better to let the courts decide on this through the development of case law.
- You can find support in case law on it.
- Case Law has clarified a lot of open questions. I would expect that any new definition (which
  might not capture future new innovations) would again need to go thoughout challenges
  and require clarifications by the CJEU which would take many, many years...
- We do not think this is a contentious issue in SPC law. Any additional definition would inevitably raise questions of interpretation that would lead to more legal disputes and references to the CJEU.
- It would seem to give focus to the issue of an SPC; the downside is that the SPC extends a
  basic patent and how can you define active ingredient only in a subsequent filing such as for
  SPC?
- "Active ingredient" is not a significant problem now, it has largely been clarified by the case law and including a definition will not assist or add any value. In fact, any new definition would give rise to new needs for interpretation by the CJEU.
- A specific definition of "active ingredient" in the Regulations would make it difficult for the law
  to adapt to technological developments in the future. Instead, it should be the role of case
  law to develop the meaning of "active ingredient" in response to new technology. For
  example, a definition requiring a pharmacological, immunological or metabolic effect would
  risk excluding products used to make a medical diagnosis, even though these are covered by
  Directives 2001/83/EC and 2001/82/EC.
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- Any new definition would necessarily raise many questions for interpretation by the CJEU and
  it is therefore preferred to leave the case law if and as needed.
- This should be aligned with Directive 2001/83/EC (as amended).
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- Now much clearer in regulatory law so not really an issue.
- The case law already provides guidance and the interpretation would in any event be case specific and thus subject to different national legislation
- Inclusion of a definition shall create a more certain legal environment
- The definitions in regulation should strive to legal certainty which would decrease uncertainty and unnecessary litigation cost
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- CJEU has provided adequate clarity in recent years. Any change to the definition will likely result in new and unforeseen issues and it will take many years for new case law to develop.
- This has been addressed in CJEU case law.

- Definition of an active ingredient has been clarified by case law, e.g. see C-11/13 where an active ingredient has been defined as having an active effect of its own. The proposed definition is circular with Art 1(b) This definition would undoubtedly lead to additional litigation and complication.
- The current scope of "product" under the Regulation is very broad and subject to expansive
  interpretation and abuse. Any definition, when proposed, should be coherent with common
  understanding and definitions favoured by WHO and EMA, based on the technical grounds
  necessary for the regulatory practices. Generally, SPC is not consistent with the key mandate
  and responsibilities of medicine regulatory agencies.
- Definition of an active ingredient has been clarified by case-law, e.g. see C-11/13 where an
  active ingredient has been defined as having an active effect on its own, the proposed
  definition is circular with Art. 1(b). This definition would undoubtedly lead to additional
  litigation and complication.
- "Active ingredient" is not a significant problem now, it has largely been clarified by case law and including a definition will not assist or add any value. Any new definition would necessarily raise many questions for interpretation by the CJEU and it is therefore preferred to leave the case law evolve organically, if and as needed.
- is now defined by case law, does not Need further clarification
- The SPC Regulation does define the "product", which is the active ingredient. The active ingredient is governed by the Community Code on Medicinal Products. Therefore, there should not be a definition in the SPC Regulation, for risk of inconsistencies with the European pharmaceutical legislation.
- A definition of "active ingredient" is already included in regulation EC 1610/96 for the
  agrochemical sector. Definition of an "active ingredient" has been clarified by case law by
  the CJEU, e.g. see C-11/13. Any new definition would necessarily raise many questions for
  interpretation by the CJEU and it is therefore preferred to leave the case law evolve
  organically, if and as needed.

### Q 45: All in all, would you favour or oppose this clarification?

- additional comments -
- The proposed clarification would require additional context (this comment also applies to the
  previous question). Furthermore, it is not practical to ask the SPC granting authorities to make
  an assessment of whether a there is a significant difference in properties relating to safety and
  efficacy.
- One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. The structure of the survey is further inconsistent as a comment box is here provided as opposed to question 27. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- The proposed wording adds some clarification but is still open to Interpretation of "significantly".
- Howver, this definition is not complete because it does not relate to biotechnological active products and biosimilars thereof.
- This definition does not seem to clarify the meaning of the term "derivatives of the substance", since it is not clear what the skilled person understands by the expression "differ significantly in properties with regard to safety and/or efficacy". Accordingly, this expression is indefinite.
   Furthermore, in the proposed clarification "esters, ethers and complexes" are redundant, since

the term "derivatives of an active ingredient" as commonly used also covers esters, ethers and complexes. Moreover, the development of a derivative of an active ingredient may be very innovative, e.g. in case a completely new synthesis route has to be developed which allows the preparation of product of similar safety and efficiency but of a much cheaper product. However, the suggested amendment would exclude the grant of an SPC for such products.

- No clarification of the law is required. It is clear that a new salt, ester etc, is considered a new chemical entity and is subject to a patent and a marketing authorisation then a SPC may be granted. Any further analysis with regard to efficacy and/or safety must be considered beyond the competence of the national patent offices.
- Clarification seems to be necessary. Currently the patent offices are responsible for taking a
  decision in each individual case in order to decide whether such a product could be
  considered a new acticve substance, which leads dissenting national practice. The
  proposed text still leaves uncertainty, for example it is not clear, that the term "derivetive"
  does not extends to different comounds that belong to the same Markush formula.
- One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. The structure of the survey is further inconsistent as a comment box is here provided as opposed to question 27. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- Again, this pharma language is not suitable in the patent field; in fact, enforcement of SPCs is (or should be) mainly legal proceedings working along the estblished principles of patent law (which have been established to foster innovation) and not based on pharma law (which have been established to protect patients from danger of new medical products)
- Anything which is covered by a separate patent, should be eligible for SPC protection. -Safety and efficacy criteria are registration requirements and are not suitable for the examination process in patent offices.
- "differ significantly" will be open to interpretation anyways so does not help
- I believe that the current caselaw now provides a reasonable degree of certainty. Any new
  definition is only likely to result in further CJEU references.
- We have seen and agree with the comments that we understand EFPIA will be submitting in response to this question. Assessing whether there is a significant difference with regard to safety and efficacy is a question for medicines regulatory bodies, not national patent offices. It is sufficient that a molecule is considered a NCE by the EMA/national authority and that there is a patent to that molecule.
- Similar to the previous question, the problems to come rest in the wording of the propsed texts, e.g. "shall be considered" and "unless the differ significantly".
- Anything which is covered by a different patent should be eligible for SPC protection if all
  criteria are fulfilled.
   Safety and efficiency criteria are registration requirements and are not
  suitable for the examination process in patent offices.
- Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- It should read to safety and efficacy
- It is impossible to accept a proposed clarification like this without any additional context (this comment also applies to the previous question). Furthermore, it is not practical to ask the SPC granting authorities to make an assessment of whether there is a significant difference in properties relating to safety and efficacy. This is a regulatory issue.

- I do not think that the fact that there must a patent SPECIFICALLY covering same should be a requirement It further leads to the question of what specifically and covering means
- It seems appropriate to mirror the dedinitions to those in the Medicines Regulation
- Introducing such a definition would require patent offices to assess a highly technical question (comparative safety / efficacy) that falls outside of their area of competence. Requiring consideration of that question would also run contrary to the objective for the SPC legislation to provide "a simple, transparent system which can easily be applied by the parties concerned" (see paragraph 16 of the Memorandum).
- and different crystalline polymorphs
- Difficult to understand the advantage of this "clarification". In our view, it follows from Recital 14 that the derivative must be a separate innovation justifying the grant of a patent. This usually requires the derivative to show improved safety and/or efficacy.
- Anything which is covered by a separate patent, should be eligible for SPC protection. -Safety and efficacy criteria are registration requirements and are not suitable for the examination process in patent offices.
- Anything which is covered by a different patent should be eligible for SPC protection if all
  criteria are fulfilled. With regard to the proposed clarification: To link the definition to
  registration requirements such as safety and efficiency is not suitable for the examination
  process in patent offices.
- It would be clearer to close this alley, and simply make the "SPC availability" dependent upon the question whether a full new medical approval is necessary or not. I don't think just because a company figures that an alternative salt works even better, should be awarde with a new SPC, if they can get a new patent on it anyway. Otherwise, we will have case laws on the term "significantly" in this context... Instead I suggest: "The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless the regulatory authorities consider the application for marketing approval such that it requires the same support with studies and data as a new chemical entity."
- The proposal will likely further confuse, instead of clarifying. It will likely cause unncessary confusions as to, for example, what is "complex", what is "derivative" other than salt or ester, who would be the person to "consider" (e.g., patent office officials, EMA officials, clinicians, scientists, patients, or a hypothetical person skilled in the art used by the patent office), how to measure "differ significantly", whether the patent office measures safety or efficicacy differently from the EMA.
- It is unclear why we are allowed to comment on this proposed clarification but not on the proposed definition of "active ingredient." This seems inconsistent with the goal of obtaining a robust analysis of stakeholder opinions. In this case, the proposed "clarification" is not a clarification, as it would raise additional questions and require further interpretation. Additionally, issuance of an SPC by a patent office should be as close to administrative in nature as possible. No patent office should have to evaluate the difference in safety or efficacy of two products, much less the significance of that difference.
- What does significantly means? How it would be decided and by whom? Please note that Directive 2001/83/EC refers to generics, meaning a different party has to demonstrate equivalence based on the already provided clinical data of the reference product. In addition, authorities check compliance.
- I do not see any rationale for this question or proposal. If a molecule is considered to be a new active ingredient and there is a patent protecting that molecule then it should, provided the other aspects of the Regulation are met, be possible to base an SPC on that patent.
- We are opposed because, the regulatory authorities will determine to what extent a new
  marketing authorization is required. And that should be the test to obtain an SPC or not.
  Patent offices are not able to determine whether derivatives "differ significantly in properties
  with regard to safety and/or efficavy".
- The proposed definition requires a knowledge and understanding of the safety and efficacy of the products concerned, which is outside the remit of any patent office. The determination

as to whether a product is a new active substance is made by the relevant medicines regulatory body. It is therefore unnecessary to include any such condition in the SPC regulation, and to do so is likely to result in uncertainty.

- I think "significantly" is not clear and I think it should be added that in addition to safety and/or
  efficacy indication should be added.
- the recital of Regulation 1610/96/EC referred to dérivatives which are the subject of patent specifically covering them. Patentability may arise from significantly different properties that go beyond safety and/or efficacy. The proposed clarification seems to limit the scope of dérivatives that could benefit from SPC protection. What would be the objective criteria to decide whether safety and/or efficacy are significantly different? grant of a new (different) marketing authorization?
- There is no need to clarify the conditions under which a derivative may be considered a new
  product in the SPC regulation, the current wording is clear enough. Moreover, safety and
  efficacy are criteria applicable to the product registration authorities according to regulation
  (CE) 1107/2009, there is no need to apply them to SPCs.
- What does "differ significantly" mean? We are creating another endless discussion with this wording.
- Some parts of this proposed text need further clarification e.g. 1.) "differ significantly": what does "significantly" mean exactly? If this is not known exactly it is impossible to say whether a specific isomer is different or is considered to be the same active ingredient. 2.) What is the basis to which the salts esters etc. are compared? Is this always the already approved active ingredient? And, in case of 2 or more already approved active ingredients which one should be chosen as basis? 3.) What does the term "derivatives" mean? Since the salts and esters and isomers etc. are listed separately they should mean someting different. An interpretation can be the chemical derivative but this can raise further questions: since in general the drugs in the same terapeutical class have similar structures (e.g. bisphosphonates) are they derivatives of each other? What separates them? If this is the "significant" differences in safety and/or efficacy we are again at the problem mentioned above in point 1.)
- "differ significantly" has to be defined
- What constitutes "differ significantly"?
- as long as these developments are not serving for evergreening
- the part of the sentence after "unless" introduces again some ambiguity into this clarification
- In my opinion it should be further clarified, who or how will assess if there is any significant difference. There are cases in which an active ingredient has received a marketing authorisation and SPC and a simple derivative has been the object of separate marketing authorisation and new SPC, however, they do not differ in safety or efficacy. The main difference is in the route of administration. However, this information is not available to the national patent offices that have granted SPC for the molecule and its derivative. Furthermore, although there are some statements in the EPAR of the molecules, EMA has not made any clear and unambiguous statement that there are no significant differences. Therefore, at the end of the day, the question needs to be assessed by national Courts that can reach at different conclusions based on expert evidence presented before them.
- "Differ significantly" appears to provide additional uncertainty
- We are not in favor of the reopening of the current SPS protection
- It would be outside the competence of national patent offices to assess safety and/or efficacy differences.
- I am not aware of any complexities in this area and so no basis to reopen this now. While there is clearly a nexus with regulatory law, there is no reason to make this expressly and the regimes are strictly speaking different and SPC law (and patent law) and should have the flexibility to sit in between the two.
- This definition is not in itself clear, either. In particular, what is "differ significantly in properties with regard to safety and/or efficacy"? A patent examiner cannot judge this.

- One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- The effort and the delay in the approval comes from finding the active and that it has safety and efficacy, even if a derivative might differ in safety and or efficacy, there should not be a delay for such development that deserves extra patent time. The reward should only be for finding a new active, not a derivative minimally changing some properties, which does not entail the risks of failure in the development. The original case law of the CJEU was clear in this regard, now this point is totally unclear and the inclussion of derivatives is being a mess.
- The text shows a clear contradiction. A new salt cannot be a new product. It is the same product.
- I would need further clarifications about the rationale behind this definition. Regulatory
  authorities do define whether a product qualifies as a "new active substance", and this
  assessment would also need to be the under the responsibility of the Regulatory Authorities.
- Patent offices have no capacity or knowledge to decide on whether a new derivative is safer
  and more effective. That question falls within the purview of regulatory agencies, and patent
  offices accept their decision as a given once a marketing authorisation issues. Introducing
  such a definition would clearly lead to additional legal disputes and references to the CJEU. In
  addition we believe that the Regulations already permit a new SPC for a derivative where
  there is an appropriate basic patent and a new marketing authorisation.
- Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety or efficacy.
- This test seems reasonable, but there are some concerns. For example, the list of derivatives should not be exhaustive, in order to allow the list to cover new technological developments in the future. Namely, the words "or derivatives of an active ingredient" should be left open to cover any type of modification to an active ingredient. It is also not clear how the new proposed clarification would be integrated into the existing Recital 14 of Regulation 1610/96/EC is this an additional requirement to the derivative being the subject of a patent specifically covering it, or is this a replacement of that language? It is also not clear when the significant differences in safety and/or efficacy would need to be demonstrated and to what standard of proof. We think applicants should be allowed to submit experimental data to show significant differences in safety and/or efficacy regardless of whether this data was included in the application for marketing authorisation or if new active substance (NAS) status has been asserted.
- Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- Any limiting definition of the active ingredient will raise additional questions. The Patent Offices
  have no experience in examining safety and efficacy as this is subject to the regulatory
  authorities.
- The alternative would be to simple regard independent patented subject matter as new "products". The the underlying patents could be challenged to remove weak IPR in the normal manner and greater certainty is given to SPC entitlement.

- One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. The structure of the survey is further inconsistent as a comment box is here provided as opposed to question 27. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- Frankly, I have not found the regulatory provisions particularly helpful so I am far from convinced that this change will help
- The word "significantly" may need to be specified. Is statistical tests proving a significant difference on one (or more?) parameters needed? And if so, what are the parameters that should be tested and proved to be significantly different?
- The clarification is unnecessary, as it already now applies through the link between the SPC Regulation and the European pharmaceutical legislation.
- The idea of including certain derivatives into the SPC directive is going into the right direction, but this should be the exception. Art. 10(2)(b) of Directive 2001/83/EC sets a standard for a generic derivative which I believe is too low. Rather, significant clinical trials should be necessary, i.e. more akin to Art. 10(3) of Directive 2001/83/EC. I would propose to define (by way of fiction) a derivative of a known active ingredient as new active ingredient if it was subject to testing of the safety and efficacy that is substantially equivalent to the standards of annex I of Directive 2001/83/EC (and related guidelines). See also ECJ cases C-195/09 and C-229/09 which set a similar hurdle.
- One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. The structure of the survey is further inconsistent as a comment box is here provided as opposed to question 27. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- The proposed clarification would create uncertainty, for example as regards what qualifies as significantly different properties. This will lead to more litigation.
- CJEU case law has clarified. Continued lack of clarity in the proposed text particularly as regards biologicals.
- We would generally favour clarification on this point, but note that the proposed wording still leaves significant uncertainty. For example, what does "differ significantly" mean? Our experience is that a similar definition used to determine whether a product is a new chemical entity for the purposes of data exclusivity has resulted in significant uncertainty.
- Anything which is covered by a different patent should be eligible for SPC protection if all criteria are fulfilled. To link the definition to registration requirements such as safety and efficiency is not suitable for the examination process in patent offices.
- We consider the SPC mechanism as a whole needs to be reviewed and eventually ended. The expanded definition of "active substance" under Regulation 1610/96/EC contradicts the scope of "active ingredient" under Directive 2001/83/EC in which derivatives are considered as the same active ingredient. Although the proposed clarification under this question might help correct the expansive interpretation of active ingredient and limit "evergreening" strategies, it still does not address the fundamental problem of allowing SPC protections in the first place. In the current proposed definition, it is also critical to give more clarity on what would qualify as 'significance', and in particular whether this refers to clinical and/or statistical significance.
- The proposed definition of an active ingredient is circular with Art. 1(b). Furthermore, it is unclear "what intended to exert", "with a view to" and "on its own" mean. This definition would undoubtedly lead to additional litigation and complication. Anything which is covered by a

different patent should be eligible for SPC protection if all criteria are fulfilled. To link the definition to registration requirements such as safety and efficiency is not suitable for the examination process in the patent offices.

- This definition would immediately raise questions as to the bounds of the term "significantly".
- One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. The structure of the survey is further inconsistent as a comment box is here provided as opposed to question 27. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule.
- This is a question for medicines regulatory bodies, not patent offices.
- No clarification necessary. This applies already, reading the SPC Regulation and Community Code together.
- Anything which is covered by a different patent should be eligible for SPC protection if all
  criteria are fulfilled. Safety and efficiency criteria are registration requirements and are not
  suitable for the examination process in patent offices.

# Q 48: When it comes to Art. 3 (a) of Regulation 469/2009/EC and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty?

#### - additional comments -

- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners and patent offices can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.
- Instead of amending Art. 3(a) of Regulation 469/2009/EC, EU Guidelines for Examination of SPCs, e.g. such as the Guidelines for Examination of SPCs of the German Patent and Trademark Office, seem to be needed. Guidelines are more flexible than the Regulations and may be further adapted in the future. To assess whether Art. 3(a) of Regulation 469/2009/EC is fulfilled, the Guidelines for Examination of SPCs may contain e.g. the following tests, which are based on the Medeva and Eli Lilly decision of the CJEU: Step 1: Is the product literally mentioned in at least one claim of the patent? If this is the case, Art. 3(a) is fulfilled. If this is not the case, Step 2 applies Step 2 (Comprises two conditions): (a) Does the product, i.e. the active ingredient or combination of active ingredients, fall within at least one claim, based on an interpretation of the claims as required by Art. 69 EPC and the Protocol on the Interpretation of the EPC, inter alia in the light of the description; and (b) Does this at least one claim permit the conclusion that it relates, implicitly but necessarily and specifically, to the product, ie. to the active ingredient or combination of active ingredients in question. If both conditions are met, Art. 3(a) is also fulfilled.
- The test if clear and should any further clarification be required the CJEU will provide said clarity. Any amendment is likely to add complexity and a lack of clarity.
- The core inventive advance test reflects stricter approach, denying second SPC for a "non synergistic" combination covered by the basic patent (ie. API plus and "off patented" active ingredient).
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners
  and patent offices can hardly be made clearer. Through the CJEU case law, the various
  questions which have arisen regarding its interpretation have now been answered, providing
  further clarity and guidance to patent offices. Decisions on the pending references should

further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.

- The infringement test is the simplest test, which would ensure legal certainty. Furthermore, in the absence of the decisions from the CJEU most practioners would have understood the wording of Art. 3 to mean exactly that.
- It should be sufficient to refer to the basic patent. The relevant test should be whether the claims of the patent are \*infringed\* and no further tests should be required.
- While we think that the "infringement test" is the right approach, we don't think an amendment of the current regulation is necessary.
- We agree with the comments that we understand EFPIA is submitting in response to this question. It is highly likely that any attempt to clarify would in fact have the opposite effect, with ensuing uncertainty. Comment: Article 3(a) is a very short and clear article, which as acknowledged by many practitioners and patent offices can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.
- The term "core inventive advance" opens up a vast field of possible interpretations, so that the legal uncertainty is transferred to the meaning of this term.
- Article 3(a) is a short and clear article, which can hardly be made clearer. Through the CJEU
  case law, the various questions which have arisen regarding its interpretation have now been
  answered, providing further clarity and guidance to patent offices. A robust test to determine
  whether a product is protected by the basis patent is needed. The infringement test is such a
  test and is already included in the established Art. 3a. Therefore no changes are necessary.
- In terms of legal certainty Art. 69 would appear to be most appropriate but tis may give rise o
  further issues
- We favor the interpretation as "core inventive advance test" (as in UK case law). There is already a pending referral to the CJEU on this.
- Whilst there is some uncertainty about how Article 3(a) is to be interpreted, it is important to note that the uncertainty: (i) affects only a relatively small number of cases (with assessment of compliance with Article 3(a) being very straightforward in the majority of cases); and (ii) is again of the CJEU's own making. With regard to point (ii) above, a perfectly workable test under Article 3(a) had been developed in the UK prior to the CJEU's decision in Medeva. That test was based upon "extent of protection" combined with the requirement for a positive claim integer to read onto each active, and is set out in the UK High Court decisions in Gilead ((2008) EWHC 1902 (Pat)) and Astellas Pharma ((2009) EWHC 1916 (Pat)). Whilst it is regrettable that the CJEU did not see fit to endorse the test set out in the above-mentioned UK case law, it is important to note the following points. Firstly, the new reference in Teva UK & Ors. will provide an opportunity for the CJEU to reconsider its position. Secondly, amendment of Article 3(a) is unlikely to help. This is not only because any new wording will require judicial interpretation (and hence introduce a new element of uncertainty) but also because there is nothing to prevent the CJEU providing rulings in connection with the new wording that yet again create chaos out of order.
- The core inventive advance test will lead to inadequate results in many situations, for instance
  regarding the possibility to base an SPC request on a formulation patent, use patent or
  method patent because in these cases the core inventive advance lies in technical features
  not related to the active ingredient. We would prefer the test proposed by Justice Warren in
  the UK High Court decision (2014)WEHC2404(Pat) (Eli Lilly v HGS).
- (1) This contradicts the rationale of the SPC regulation and the rationale developed in Ely Lilly case. (2) We need a robust test to determine whether a product is protected by the basic patent. This is the infringement test, no further change is needed. (3) Incentive step assessment is already done for the basic patent and should not be assessed in the SPC application phase again. This test should be avoided. In case, the case law of the CJEU in general should be taken into account, the following slight amendment is proposed: Art. 3.1

- (a)... the product falls in the claims of the basic patent in force and is subject matter of the basic patent in force or an equivalent thereof...
- By means of the current case law of the CJUE, I understand that we already have legal certainty. A new wording of the Art 3 (a) of Regulation 489/2009/EC will give rise new interpretation and new case law with a new long term of uncertaintly.
- Art. 3(a) should not be reviewed in isolation but together with the other criteria in Art. 3. All four conditions of Art. 3 are already balanced. With regard to the specific suggestions: Re paragraph 1) The rationale of the SPC regulation is to extend the basic patent term for a given product, which is covered by a marketing authorization and thus, will always result in a SPC for only one product, while the basic patent might be broader. Thus, applying, a 123(2) test does not seem to be suitable and could lead to wrong results as it does not sufficiently take this rationale into account. Re paragraph 2) A robust test should be used to determine whether a product is covered by a patent and falls under the scope of the claims of a patent. The infringement test is such a robust test. Re paragraph 3) The inventive step is analyzed in the examination phase for the basic patent and should not be repeated.
- it should be specified that the product must not only be covered by the "basic patent's" claims (infringement test) but must also be directed to the product be it a new substance or a new indication or a new combination. If the combination is just any obvious combination (that in itself is not inventive) why would such a combination deserve a SPC? Of course it will be questioned, what falls under the core inventive advance, and what doesn't but this is probably the normal insecurity of the patent world.
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners
  and patent offices can hardly be made clearer. Through the CJEU case law, the various
  questions which have arisen regarding its interpretation have now been answered, providing
  further clarity and guidance to patent offices. Decisions on the pending references should
  further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered
  as a whole and not only as single decisions decided based on the specifics of a given case.
- Article 3(a) of Regulation 469/2009/EC is clear and concise and still there have been CJEU decisions related to its application in certan circumstances. Adding words will not provide additional clarity, especially given the clarity that has already been achieved by the referrals to the CJEU. Rather, in an attempt to "clarify" the regulation, only more uncertainty would be created as the new words would be parsed and their meanings debated by the courts. Furthermore, none of the proposed amendments are better aligned with the stated purpose of the regulation than the current regulation is. If the goal is to compensate loss of "effective (patent) protection" for the product, then there is no need to try to narrow either the "products" or "patents" falling under the regulation, espcially when only one patent per product may be extended.
- Personally I believe that the second and fourth option, have been proved insufficient. There
  are associated problems with the first and the third. I would lean towards the first one even
  though remains subjective because the third may lead to extensive patent filings, in the
  future.
- Introducing a definition would introduce more uncertainty, The case law is developing in this
  area and this point is at issue in only a very few cases.
- As we are a plant protection company we answered this question from the perspective of the Plant protection SPC regulation. There is nothing in either the medicinal or plant protection regulation that refers to any inventive advance test
- It is clear from the CJEU case law that it is difficult, if not impossible, to have a single test which
  adequately and fairly covers all situations. However, the body of case law provides
  reasonably clear criterion in relation to Art 3(a) in a variety of situations, and we expect this
  clarification to continue in relation to currently pending cases.
- most favourable of all, but not sure whether it is a sufficient clarification.
- Reference to national provisions is likely to induce divergence in the practice of the national
  offices. With this new wording, provisions should also be introduced to prevent filing of 'hostile'
  SPCs by patent owners that are not associated with the pharmaceutical development, which
  was made possible following decision C-181/95.

- Art 3(a) should be worded so that the product is protected when the product as such is
  protected, or the therapeutic use of the product that is defined in the claims and corresponds
  to the use in the MA is protected. There is then a distinction between the product and the
  medicinal product. That is, even if the medicinal product is protected, the product is not
  protected if it, or its therapeutic use, if it is not disclosed in the claims. (cf. MIT-case from ECJ) A
  certain leeway in form of functional definition of the product (e.g. substance A in
  combination with compund with activity B) should be permissible.
- The difficulty is that different tests work well for different situations. So, for example, the "core inventive advance" test works well for combination products but does not work at all for a Markush formula. This is because, for a Markush claim, it is assumed that all compounds within the claim are part of the invention (otherwise the claim would not be granted), and as a result the test does not add anything to the infringement test for a Markush claim. This is why it is better not to amend the regulation but to encourage the CJEU to have a nuanced approach to interpretation based on the facts of the case. This does not help with legal certainty but is the only way to strike a fair balance between competing interests based on the evolution of technology and the fact that we cannot predict all of the issues that will arise in the future.
- The CJEU has clarified some of the legal uncertainty in this area. All of the proposed alternatives would raise more questions than they answer.
- An infringement test is too broad. A disclosure test is too narrow. There is no need to amend to
  allow the core inventive advance, which, if the CJEU so finds, could be adopted by caselaw
  in the appropriate circumstances (with a pending referral in Teva already awaiting such a
  response).
- Very difficult to find the right definition
- Article 3(a) is a very short and clear article, which can hardly be made clearer. Through the
  CJEU case law, the various questions which have arisen regarding its interpretation have now
  been answered, providing further clarity and guidance to patent offices. Decisions on the
  pending references should further add to this clarity. In addition, the case law of the CJEU on
  SPCs should be considered as a whole and not only as single decisions decided based on the
  specifics of a given case. In addition, we see strong limitations with all the suggested
  amendments
- There is already quite good certainty on the issue.
- CJEU has already given a lot of guidance, I don't see the need to re-open discussions.
- There is a great deal of case law in the EU on patent infringement. Thus, it would be relatively
  easy to determine if Art. 3(a) of the Regulation is fulfilled. This legal certainity will even be
  increased in the future, when the UPC as an EU patent infringement court comes into force.
  All other options also sanction possible drafting defects in the original patent application,
  which the patentee should not be held accountable for.
- The CJEU jurisprudence in this area has developed significantly in recent years and is broadly settled. Each of the new suggestions above would lead to a significant loss of clarity in the law and give rise to many new disputes. No one knows what the core inventive advance test means, even in the UK. The infringement test has been clearly rejected by the CJEU as too wide. A directly and unambiguously test would render pointless any patents that do not explicitly and exhaustively claim active ingredients that are the subject of marketing authorisations which would exclude many valuable life-saving inventions from receiving SPCs.
- Article 3a is clear and can hardly be made clearer. CJEU case law helps to clarify any need for interpretation when art 3a is applied to different factual situations.
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners and patent offices can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.

- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners and patent offices can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.
- If SPC enttilement is not settled only on the basius if independently valid patent claims that there is an equitable trade off in saying SPCs are available only for the subject matter the patentee has enabled.
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners
  and patent offices can hardly be made clearer. Through the CJEU case law, the various
  questions which have arisen regarding its interpretation have now been answered, providing
  further clarity and guidance to patent offices. Decisions on the pending references should
  further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered
  as a whole and not only as single decisions decided based on the specifics of a given case. In
  addition, we see strong limitations with all the suggested amendments.
- Terrible proposals do they understand what this subject is about. There are problems with
  combinations products, which Medeva more or less solved (for combinations) and then made
  it difficult to follow as far as stand alone products are concerned much of this could have
  been avoided if the CJEU had understood some of the basic concepts of patent law. But
  none of the proposals is any better and frankly they will create unnecessary uncertainty
- The interpretation would still be case-specific. If the examination of whether a certificate can
  be granted includes detailed analysis of how the product is protected by the basic patent,
  then is no longer a "simple procedure" to grant certificates and therefore, it becomes even
  more difficult to harmonise
- No amendment is required. The current ambiguities created by the CJEU case law (as
  evidenced by proposed answer (1) from the HGS/Eli Lilly case) are not helpful, but
  unavoidable in structure as long as patent infringement is not harmonized on a European
  level. Trying to bridge that lack of harmonization through the SPC Regulation is doomed to fail
  from the outset, and would only create further uncertainties (as evidenced by the finding in
  the HGS/Eli Lilly case).
- Art 69 EPC is subject to national interpretations and increases uncertainty
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners and patent offices can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.
- The UK approach requires in-depth knowledge of the prosecution to assess the "core inventive advance". This adds too much complexity in SPC prosecution and results in legal incertainty since national patent offices may reach different conclusions. In addition, the "core inventive advance" may change if new prior art is found in e.g. post-grant proceedings, i.e. the assessment of Art. 3a may change over time. This is improper. New prior art should only have an impact on the patentability not the eligibility to an SPC as such (i.e. on the assessment of Art. 3a).
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners and patent offices can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments.
- I think the definition should be slightly amended so it refers to the national principles of patent law rather than only Art. 69 EPC and its corresponding national provisions. In other words, I think the definition should read: "The product is protected when it falls under the scope of

protection of the basic patent pursuant to non-Community principles of patent law, namely Art. 69 EPC and its corresponding national provisions."

- The current text is very clear, and the CJEU case law has provided further clarity. Amendments will lead to new uncertainty and it will take many years for new case law to develop,
- Any amendment to the regulation comes with a risk of creating greater legal uncertainty
  depending upon the precise wording of any new provisions. There are severe concerns about
  attempting to re-open scrutiny of the regulation given the length of time and compromise
  needed to achieve the current version, which serves an important purpose.
- The specific implementation of this test in the wording of the Regulation will need to be very carefully drafted, to avoid further uncertainty in determining that the "core inventive advance" means.
- Art. 3(a) should not be evaluated in isolation but together with the other criteria in Art. 3. All four conditions of Art. 3 are already balanced. Art. 123(2) EPC test in given answer (1) does not fit with the rational of the SPC regulation and does not give clear criteria. The infringement test is already included in the established Art. 3a, that is because no changes are necessary as in given answer (2). Paragraph given in answer (3) does not lead to further clarity and should be avoided.
- Art. 3 (a) should not be evaluated in isolation but together with the other criteria in Art. 3. All four conditions of Art. 3 are already balanced. Art. 123(2) EPC test in given answer (1) does not fit with the rationale of the SPC regulation and (2) does not give clear criteria. The infringement test is already included in the established Art. 3a, that is because no changes are necessary as in given answer (2). The paragraph given in answer (3) does not lead to further clarity and should be avoided.
- Article 3(a) is a very short and clear article, which as acknowledged by many practitioners
  and patent offices can hardly be made clearer. Through the CJEU case law, the various
  questions which have arisen regarding its interpretation have now been answered, providing
  further clarity and guidance to patent offices. Decisions on the pending references should
  further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered
  as a whole and not only as single decisions decided based on the specifics of a given case. In
  addition, we see strong limitations with all the suggested amendments.
- No amendment is needed. There is clearly ambiguity introduced by somewhat unfortunate CJEU case law. However, that case law clearly stems from the uncomplete harmonization of patent (infringement) law in the Member States and a directly applicable (and thus harmonized) SPC Regulation. It is not possible to compensate the lack of harmonization on the patent law side through the SPC Regulation. This would only create further confusion. The finding of the CJEU in the HGS/Eli Lilly, which can only be called byzanthine, is a perfect example and should definitely not serve as a reference for legislation.
- Article 3(a) is a short and clear article, which can hardly be made clearer. Through the CJEU
  case law, the various questions which have arisen regarding its interpretation have now been
  answered, providing further clarity and guidance to patent offices. A robust test to determine
  whether a product is protected by the basis patent is needed. The infringement test is such a
  test and is already included in the established Art. 3a. Therefore no changes are necessary.

Q 49: In your view, should all variations of a marketing authorisation constitute a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC11 or not?

- As mentioned before, a new SPC Regulation shall be created. This new SPC Regulation shall cover all types of marketing authorisations.
- Some variations are very minor changes and thus not all variations should be considered a new marketing authorisation.

- The CJEU has not expressed (yet) unreasonable interpretations with respect to MAs and the
  effect whether material changes to the MA make it a new MA from the SPC-regulation's point
  of view
- Not relevant for agrochemical sector.
- Recent CJEU caselaw (Neurim) allows for SPCs on previously approved products for new
  marketing authorisations where the fact-pattern justifies this. We do not see the need for any
  change to the Regulation.
- Not ALL variations will constitute a new marketing authorisation for the purposes of Art 3(b) and (d) of the SPC Regulation. However, some variations should constitute a new MA for the purposes of the SPC Regulation, for example, in situations when the variation consists of a new indication which corresponds to a separate patent right.
- Not all variations will constitute a new marketing authorization for the purposes of Art. 3(b) and (d) of the SPC Regulation. However, some variations should constitute a new MA for the purposes of the SPC Regulation.
- Whether there is a completely new authorisation or a variation of an existing authorisation, the question of SPC eligibility should turn on matters of legal substance, and not form. In this respect, what should be decisive is: which product (or which new use of a product) is brought to the market for the first time by way of the authorisation / variation in question; and whether that product (or that new use) meets the requirements for SPC eligibility.
- If an SPC application is directed at an innovative variation of an existing product, the SPC should not be rejected for the formal reason of Art. 3(b).
- Type 1a and 1b variations of regulation 1234 / 2008 / EC include only small changes, that is because it should not considered for the marketing authorisations.
- Of course not! An SPC awards the years and years of developing a drug from scratch, not simply each and every clinical trial!
- It's not that I have no opinion. I do have an opinion! But my opinion is neither yes nor no. Rather, my opinion is that the answer depends on the variation. If the variation is merely e.g. the variation in the address of the API supplier then the resulting MA does not qualify as a new MA for the purpose of an SPC. If the variation is much more substantial then the resulting MA may qualify as a new MA for the purpose of an SPC.
- Not all variations will constitute a new marketing authorisation for the purposes of Art. 3(b) and
  (d) of the SPC Regulation. However, some variations should constitute a new MA for the
  purposes of the SPC Regulation, for example, in situations when the variation consists of a new
  indication which corresponds to a separate patent right.
- Not "all" marketing authorizations do or should constitute a "new" marketing authorization, but some should. As mentioned previously, the key is the purpose of the SPC regulation. For example, where there has been significant time/investment required to obtain approval of the variation, the goal of compensating the MAH for loss of patent term during that period remains relevant.
- This is an overly simplistic question.
- Again we are answering from a plant protection point of view. If the advancement is minor, then it should not take the regulatory authorities a lot of time to review and hence the potential duration of the SPC would be zero
- Some should.
- There are certain situations where variations may support a new SPC, for example, where a new indication is approved that is covered by a patent
- Only those new MAs that show a new therapeutic indication or new treatable population should be considered new
- I find it very hard to see what this question is getting at. What does "new" mean? Art 3(b) requires a marketing authorisation in the country (not necessarily a "new" one). Art 3(d) requires a "first" authorisation, which might not be the first just for the active, per Neurim. If this

is saying that you can somehow get a clean slate for every new marketing authorisation under Art 3(b) and (d), the answer is no. However, you need to look at Neurim and decide how far it goes. Can every single variaion be a "new application" according to Neurim? I think the answer is no. But some of them can.

- Certain variations should constitute a new marketing autorisation for the purposes of the SPC Regulation, e.g. a new indication protected by a new patent (see Neurim decision)
- Not all variations will constitute a new marketing authorisation for the purposes of Art. 3(b) and
  (d) of the SPC Regulation. However, some variations should constitute a new MA for the
  purposes of the SPC Regulation, for example, in situations when the variation consists of a new
  indication which corresponds to a separate patent right
- A new formulation might not justify to be considered as a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC but a new therapeutic indication (extended and long clinical studies) should be considered as a new marketing authorisation for the purposes of Art. 3(b) and (d).
- Where a variation has required the submission of additional safety and efficacy data (such as Type II variations) and there is an appropriate basic patent, there are grounds to argue that an SPC should be available. This would encourage the development of additional indications and presentations of pharmaceuticals that lead to genuine patient benefit.
- Not all variations will constitute a new MA for the purpose of articles 3b and 3d of the SPC regulation.
- Any type of marketing authorisation should be useable in principle, but the validity of the SPC under Article 3(d) SPC Regulation would need to be determined with reference to the scope of the basic patent in accordance with CJEU decision C-130/11 (Neurim). Specifically, following Neurim, under Article 3(d) (and Article 13(1), which must be considered together) "the MA referred to in Article 13(1) of the SPC Regulation is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC" (Neurim section 30). It would be helpful to confirm the generally applicable nature of this test e.g. via guidance from the Commission.
- Not all variations will constitute a new marketing authorization for the purposes of Art. 3(b) and
  (d) of the SPC Regulation. However, some variations should constitute a new MA for the
  purposes of the SPC Regulation, for example, in situations when the variation consists of a new
  indication which corresponds to a separate patent right.
- Not all variations will constitute a new marketing authorisation for the purposes of Art. 3(b) and
  (d) of the SPC Regulation. However, some variations should constitute a new MA for the
  purposes of the SPC Regulation, for example, in situations when the variation consists of a new
  indication which corresponds to a separate patent right.
- Some but not necessarily each of the different types of variations will meet the requirements of the Regulation. Differentiation will be required. The guiding decision is the Neurim decision.
- Not all variations will constitute a new marketing authorisation for the purposes of Art. 3(b) and
  (d) of the SPC Regulation. However, some variations should constitute a new MA for the
  purposes of the SPC Regulation, for example, in situations when the variation consists of a new
  indication which corresponds to a separate patent right.
- Provided that clinical trials was needed for approval of the variation of the original MA
- Only those which entail significant clinical trials, as indicated for the question regarding new derivatives.
- Absolutely not. This will lead to innovator companies being able to obtain an SPC on
  practically every patent covering a product (including polymorph, salt, formulation, use,
  active ingredient process), simply by making a number of individual minor variations to the
  MA.
- Not all variations will constitute a new marketing authorisation for the purposes of Art. 3(b) and
  (d) of the SPC Regulation. However, some variations should constitute a new MA for the
  purposes of the SPC Regulation, for example, in situations when the variation consists of a new
  indication which corresponds to a separate patent right.

• This question is too broad-brush. Some variations of a marketing authorisation are functionally equivalent to a new marketing authorization and therefore should constitute such for the purposes of Art. 3 (b) and (d) of the SPC Regulation.

Q 50: In your opinion, should changes that require an extension of the marketing authorisation be considered to be a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC12 or not?

- If the changes are due to material changes in the MA (see e.g. in a "Forsgren-like case" (C 631/13))
- Not relevant for agrochemical sector.
- Recent CJEU caselaw (Neurim) allows for SPCs on previously approved products for new
  marketing authorisations where the fact-pattern justifies this. We do not see the need for any
  change to the Regulation.
- We have seen and agree with the comment that we understand EFPIA will be submitting in response to this question. The answer could be either yes or no depending on the circumstances and nature of the extension. The question is unclear and thus it is not possible to give a definitive answer.
- The question is simplistic as it is neither yes or no in all cases.
- A new MA will simplify in a great extent examination by National Offices.
- This may lead easily to "evergreening" strategies if allowed.
- Please see the comments provided in response to the previous question.
- We would prefer to answer "Yes, in some cases"
- If an SPC application is directed at an innovative extension of an existing product, the SPC should not be rejected for the formal reason of Art. 3(b).
- Every invention which can give raise to a new patent should in principle be eligible for a SPC if all conditions are fulfilled.
- The question is simplistic as there are many different types of extensions and it is neither "yes" or "no" in all cases. Where questions arise, these can be addressed by the CJEU. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable.
- Assessment of whether an extension of the marketing authorization can be considered to be a new marketing authorization should be made on a case by case basis
- While it may be appropriate in some cases to consider an extension to be a new MA, this
  cannot be said to be the case for every extension. There has been CJEU case law generated
  that provides guidance with respect to when an extension may be a new MA. This is
  sufficient.
- Again this question is too simplistic as there are several forms of changes that lead to an
  extension of a marketing authorisation.
- We answered "no opinion" because we are in the plant protection industry
- There are some situations, such as Neurim in which an extension should count as a new.
- See comments to previous question. I would not say that ANY extension would satisfy Neurim. But some will. I am not sure if this is what the question means.

- see my comment to the last question
- Only if it is connected to an additional patent protection for the product/combination covered by the extended marketing authorisation (MA) it should qualify for a new MA!
- This question is not clear enough for me.
- A new formulation might not justify to be considered as a new marketing authorisation for the purposes of Art. 3(b) and (d) Regulation 469/2009/EC but a new therapeutic indication (extended and long clinical studies) should be considered as a new marketing authorisation for the purposes of Art. 3(b) and (d).
- This question ignores that there are many different types of extensions. Again where there is an appropriate basic patent and new safety and efficacy data has been required, it could be argued that an SPC is warranted. Again this would be to the benefit of patients.
- where a question for a specific situation arises out of these articles clarification can be left to case law
- Yes, with the understanding that an "extension of the marketing authorisation" is an extension application according to Annex 1 of Regulation 1234/2008, namely changes to the active substance(s); changes to strength, pharmaceutical form and route of administration; or other changes specific to veterinary medicinal products to be administered to food-producing animals, or change or addition of target species. Also with the understanding that the Neurim test specified in the preceding question is also required in order for the underlying SPC application based on the variation to comply with Article 3(d) ("the MA ... is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC")
- The question is simplistic as there are many different types of extensions and it is neither yes or no in all cases. Where questions arise, these can be addressed by the CJEU. A marketing authorization can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable.
- The question is simplistic as there are many different types of extensions and it is neither yes or
  no in all cases. Where questions arise, these can be addressed by the CJEU. A marketing
  authorisation can be considered as new only subject to a specific set of factors, as indicated
  in Neurim, and a SPC should therefore be available only where these are fulfilled and to the
  extent the object of the extension is patentable.
- Some but not necessarily each of the different types of extensions will meet the requirements of the Regulation. Differentiation will be required. The guiding decision is the Neurim decision.
- The question is simplistic as there are many different types of extensions and it is neither yes or no in all cases. Where questions arise, these can be addressed by the CJEU. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable.
- Provided that clinical trails were needed for extending the MA
- The question is simplistic as there are many different types of extensions and it is neither yes or no in all cases. Where questions arise, these can be addressed by the CJEU. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable.
- Again, this question is too broad-brush, but in general, extensions of a marketing authorisation
  are functionally equivalent to a new marketing authorization and therefore should constitute
  such for the purposes of Art. 3 (b) and (d) of the SPC Regulation.

Q 51: In your view, should any "type II variation" constitute a new marketing authorisation for the purposes of Art. 3(b)14 and (d)15 Regulation 469/2009/EC or not?

- Except in one case where the type II variation corresponds to a new therapeutic indication. In that situation, the variation might be considered as a new MA enabling the filing of SPC on the product. Such a SPC should have a shorter duration than a SPC on a new chemical entity.
- Not all Type II variations should be considered new marketing authorisations, however, in certain circumstances then a Type II variation should be considered a new MA.
- Not relevant for agrochemical sector.
- Assuming that this poses significant regulatory requirements that warrant additional protection
- Recent CJEU caselaw (Neurim) allows for SPCs on previously approved products for new
  marketing authorisations where the fact-pattern justifies this. We do not see the need for any
  change to the Regulation.
- we have seen and agree with the comments that we understand EFPIA will be submitting in response to this question. Comment: The question is simplistic as it is neither yes or no in all cases. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or line extensions) for the change should not have any bearing on the availability of the SPC.
- The question is simplistic as it is neither yes or no in all cases. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or extensions) for the change should not have any bearing on the availability of the SPC.
- Type II variations are not regarded as a homogeneous category concerning only large changes, e.g. new indication.
- Please see the comments provided in response to the previous two questions.
- We would prefer to answer "Yes, in some cases"
- A further decomposition would not be in line with the current SPC regulation that already gives a definition what should be considered to be product which is eligible for SPC protection.
- An SPC awards the many years of developing a drug from scratch, not each and every clinical Trial or new development.
- The question is simplistic as it is neither "yes" or "no" in all cases. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or line extensions) for the change should not have any bearing on the availability of the SPC.
- Some type II variations may constitute a new MA and others may not. Thus, it is uncertain how best to answer this question.
- Whether or not a variation of a marketing authorisation should constitute a new marketing authorisation will depend on the specific circumstances of that case. Some type II variations will, e.g. if the Neurim criteria are fulfilled, and others will not.
- We answered "no opinion" because we are in the plant protection industry
- Same comment as in question 50.
- This should be a case-by-case decision depending on the facts of the particular situation.
- a type II variations appears to possibly constitute a patentable invention. Hence it should be considered as a new MA

- Again: what does "significant impact" mean? this is not well-defined term which can be used in IP
- Again, it is difficult to say that in every case such an MA extension should automatically qualify for Neurim, if that is what this means. But I do not understand the question.
- see my comment to the question before the last question
- Not any "type II variation" should constitute a new marketing authorisation. The "Neurim decision" provides guidance in the right direction.
- This should have no bearing on the availability of an SPC.
- This is a matter for case law development. The CJEU already recognises this may be possible in the Neurim case. No amendment of the Regulations appears to be needed.
- A MA can be considered to be new only subject to a specific set of factors, as indicated in the Neurim CJEU decision, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where further questions arise, these can be addressed by the CJEU
- Yes, with the understanding that the Neurim test specified in the preceding question is also required in order for the underlying SPC application based on the variation to comply with Article 3(d) ("the MA ... is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC")
- The question is simplistic as it is neither yes or no in all cases. A marketing authorization can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or line extensions) for the change should not have any bearing on the availability of the SPC.
- The question is simplistic as it is neither yes or no in all cases. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or line extensions) for the change should not have any bearing on the availability of the SPC.
- Some but not necessarily each of the three different types of type II variations will meet the
  requirements of the Regulation. Differentiation will be required. The guiding decision is the
  Neurim decision.
- The question is simplistic as it is neither yes or no in all cases. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or line extensions) for the change should not have any bearing on the availability of the SPC.
- "Yes", with the qualifiers posted before
- Absolutely not. This will lead to innovator companies being able to obtain an SPC on
  practically every patent covering a product (including polymorph, salt, formulation, use,
  active ingredient process), simply by making a number of individual Type II variations to the
  MA for example by changing formulation or changing an API route of synthesis.
- The question is simplistic as it is neither yes or no in all cases. A marketing authorisation can be considered as new only subject to a specific set of factors, as indicated in Neurim, and a SPC should therefore be available only where these are fulfilled and to the extent the object of the extension is patentable. Where questions arise, these can be addressed by the CJEU. In any case, the technical regulatory basis (variations or line extensions) for the change should not have any bearing on the availability of the SPC.

 Again, this question is too broad-brush, but in general, type II variations of a marketing authorisation are functionally equivalent to a new marketing authorization and therefore should constitute such for the purposes of Art. 3 (b) and (d) of the SPC Regulation.

Q 52: In the decision 'Neurim C-130/11',16 the CJEU set out the conditions under which a "different application of the same product" meets the requirements for SPC eligibility. Do you agree with this case law?

- Because this Decision is not consistent with the current Regulation N°469/2009 with respect to
  Article 4 and Article 3 d) and the wording "applications" in Neurim is not clear (does it refer to
  new therapeutic indications only?). However, we are in favor of SPCs based on a new
  therapeutic indication with proviso that the Regulation be amended.
- There is a misconception in the judgement regarding the answer to questions 4 and 5. The full application of article 8(3) of the Directive requires the applicant to submit data on clinical trials and do the investments in money and time that the SPC Regulation purports to honour with extra exclusivity. In this case Neurim had to file a full application as it concerned the use of melanin was for human use and the previous application was for sheep. The MEB did not accept, for obvious reasons, that reference could be made to the old dossier for the veterinary product.
- I find the reasoning hard to follow in light of the previous case law of the CJEU
- A plain reading of the decision in Neurim leads to the conclusion that the only relevant hurdle for SPC eligibility is establishing that the MA relied upon is for a "different application" of the active ingredient. This is because there is no (explicit) requirement in Neurim for the patent that protects the "different application" to be different from that used as the basis for an earlier SPC to the same active ingredient. Thus, Neurim appears to make it possible to use a single patent to secure "double SPC protection" for the new use of the active ingredient. This is because that new use will be protected by both: (a) an earlier SPC, based upon the 1st MA for the active ingredient (the scope of which SPC, according to the provisions of Article 4, will expand to encompass the newly authorised use of the active ingredient); and (b) the later, "Neurim-style" SPC based upon the subsequent MA for a "different application" of the active ingredient. It is important to note that such "double protection" is not necessarily problematic. This is because there are circumstances in which it is arguable that: a "different application" of an active ingredient is deserving of protection by way of a separate SPC (potentially having a longer duration); and it would be unfair to make that separate protection available only where there is a separate patent. However, my concern is that the judgement in Neurim does not lend itself to rewarding (and hence incentivising the development of) only those new "applications" of products that the original SPC legislation had in mind.
- The Neurim decision is so unclear and is interpreted so differently in different states that it is not possible for me to reply whether I agree
- I do not believe there is full consensus in how to interpret Neurim, so it is not possible to say whether I agree or not
- I agree with it in principle, but regret that the CJEU did not deal directly with the conflict that the decision creates with their earlier cases, in particular MIT and Yissum. The CJEU should not just have ignored this conflict in the way that they did, but should have either said that those earlier cases were wrong or explained why they did not apply.
- SPC protection should be generally extended to new and innovative second medical uses
- Yes, with the understanding that the principle of a "different application" is not limited to a
  different therapeutic indication, or a different medical use, but also covers, for example,
  formulations (Neurim itself concerned a formulation patent) and combinations of active
  ingredients, if patentably innovative. Thus, the Neurim test applies regardless of the type of
  new application that was patentable and then lost effective patent term due to a delay in

authorisation (i.e. "the MA ... is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC").

- Yes although the implications of the decision are not clear. And it seems inconsistent with some earlier case law, such as MIT
- The findings of the CJEU in Neurim are fundamental clarifications on the scope of the SPC Regulation and pivotal for the fostering of all development objectives of the pharmaceutical industry. As set out by the CJEU, the litmus test is whether the basic patent covers the new application only, but not the earlier use. We note that a different application may also mean different formulations, different routes of application, better efficacy, better compliance, different subgroups, etc. not just new indications.

## Q 55: The case law of the CJEU is currently not clear with respect to third-party marketing authorisations: Which of the following clarifications would you prefer?

- The owner of the basic patent may be e.g. a university, which may have invented a
  pioneering technology. In this case, it seems to be justified that the owner of the basic patents
  profits from the extended protection of the product by obtaining additionally an SPC based
  on his licensee's marketing authorisation.
- We do not view there is a lack of clarity in the law.
- This is a topic which should be solved by any whatsoever SPC reform. Third Party SPC issue was not in mind when the SPC regulation was drafted and came into force. This was introduced later by the CJEU with "milestone" decisions. Now we are faced with a flood of SPCs for a given product, also to the disadvantage of the product owner. It should not be allowed for a Third Party to get an SPC for a product which is owned by another company. The ownership should be defined as the MAA holder. If there is only a selection possible for the two options mentioned, the second option should be selected.
- Please note that I do not believe that the current caselaw is unclear.
- We agree with EFPIA's comments on this question. First, we do not agree the case law is unclear. To the extent that it is unclear, it should be clarified by its author, the CJEU. Second, there should be an option "none of the above" which is different from "no opinion" as our opinion is that neither is considered adequate. It is also an issue for licence agreements, not a SPC issue.
- Do not agree that the case law of the CJEU is unclear.
- A patentee should not be allowed to refer to a 3rd party MA
- Any other Approach would likely to be contrary to the purpose of the SPC regulation
- This is not an area where I believe that clarification is required. This is because the CJEU's decision in Biogen adequately deals with this question.
- We disagree with the assumption that the case law is unclear.
- In principle, we believe that requiring the consent of the MA holder is a sensible option. However, the matter is so complex that we are concerned that such a requirement could lead to inadequate results in specific circumstances.
- No further clarification deemed to be necessary. Further, it is not a specific problem to the SPC regulation; it may already arise under the basic patent term. Consent of the third party may be considered and obtained under Art. 8 of the current SPC regulation.
- I see no reason why one product's approval should give reason for two different patents to be
  extended. If the companies collaborate they should decide amongst each others which

patent they would like to extend. Simplify the system to make it clearer. One SPC per product should be the aim.

- First, we do not agree the case law is unclear. To the extent that it is unclear, it should be clarified by its author, the CJEU. Second, there should be an option "none of the above" which is different from "no opinion" as our opinion is that neither is considered adequate. It is also an issue for licence agreements, not a SPC issue.
- We do not think formal clarification is required. However, we agree that "The applicant may only refer to a third-party marketing authorisation when the third party is in agreement and evidence of his/her consent is included in the application." Clearly, the purpose of the SPC regulation is not fulfilled by allowing someone to seek an SPC without the permission of the marketing authorization holder (MAH), since it is the MAH who has made the necessary investment (and taken the concomitant risk) to bring the medicine to patients.
- I don't believe the case law of the CJEU is unclear on this point.
- as it hardly happens in our industry, we do not think it would require any additional legislation
- I do not agree that the case law in this regard is unclear.
- I do not understand why a patentee can refer to another company's MA. The point of the SPC is to give back time of the lost protection due to the lengthy process of obtaining an MA: If the company has not obtained an MA, why should it be able to obtain an SPC?
- Applicant (or agency) informs holder.
- This is the fairest option, as otherwise the patentee takes advantage of all of the work of the MA holder for free, but the MA holder will probably still need a licence from the patentee to exploit his authorisation. With this option, both parties must effectively licence the other.
- None of the above.
- This should be regulated via additional case law!
- We disagree that case law is unclear. In any case, if it were, it should be clarified by the CJEU itself. Second, there should be an option "none of the above" which is different from "no opinion" as our opinion is that neither is considered adequate. It is also an issue for licence agreements, not a SPC issue.
- The CJEU case law is not perfect but realtively clear for the vast majority of the situations.
- It is very common that smaller pharmaceutical companies are responsible for the development of the drug (and also the initial patent filing) but that the actual marketing authorization and distribution is handled by a bigger partner (especially if the patentee is a non-EU company). In these cases, where marketing authorization holder and patentee are not identical, no further administrative burdens should be placed on the patentee, who is entitled to obtain an SPC as his licensing revenues only flow starting from the commercialization of the product by the licensee.
- We do not think the case law is unclear. This is currently permitted. If there is a desire that this
  position should be changed it is clear that the CJEU would be willing to clarify the law in this
  area with an appropriate case. The suggestions above would not adequately address this
  issue since they fail to recognise that the holder of the basic patent and the marketing
  authorisation are different companies in most instances. What matters is the nature of their
  relationship, not merely that they are different. No amendment of the Regulations is therefore
  needed.
- The current CJEU case law is clear.
- There are arguments either way on this topic. Placing restrictions on applicants using third-party marketing authorisations would need to accommodate small start-up companies who cannot obtain their own marketing authorisation, but have still put a great deal of effort into the research and development of a product resulting in a patent with reduced effective term due to regulatory delays. There is also a risk that a holder of a marketing authorisation who infringes a patent could demand an unreasonable licence from a patentee in exchange for allowing the patentee to gain an extra 5 year term of protection with an SPC. In any case, it

- would be very complex to implement substantive requirements for the ownership of the marketing authorisation.
- We do not agree the case law is unclear. To the extent that it is unclear, it should be clarified
  by its author, the CJEU. We would prefer the CJEU to continue its clarification process
  commenced in Lilly HGS case to the effect that the applicant may only refer to a third-party
  marketing authorisation when the third party is in agreement and evidence of his/her consent
  is included in the application.
- First, we do not agree the case law is unclear. To the extent that it is unclear, it should be clarified by its author, the CJEU. We would prefer the CJEU to continue its clarification process commenced in Lilly HGS case to the effect that the applicant may only refer to a third-party marketing authorisation when the third party is in agreement and evidence of his/her consent is included in the application.
- There are various scenarios which do not allow voting for the one the three options exclusively. The situation becomes more complex in case of licenses.
- First, we do not agree the case law is unclear. To the extent that it is unclear, it should be clarified by its author, the CJEU. Second, there should be an option "none of the above" which is different from "no opinion" as our opinion is that neither is considered adequate. It is also an issue for licence agreements, not a SPC issue.
- The question and statements suggest the the survey has misunderstood the basic concepts. At present, the applicant can refer to a third party MA without the consent of the third party. Fair when there is a licence from third party to applicant, and applicant has done development work. But is it fair when applicant has not taken any part in the development of the product in question? I would say not
- Solution 1 pose the problem, that a holder (A) of a basic patent but without a marketed product may prevent the holder (B) of a MA in marketing its product if this product falls within the scope of the certificate granted to A. However, this could be circumvented by inserting a requirement that the holder of a certificate should also have invested time in development of a product falling within the scope of the MA. In solution 2 above (the holder of the MA should agree to the reference), the holder of a MA may refuse to agree and thereby effectively keeping competitors off the market.
- 1 NCF should have 1 SPC
- "Consent" by the holder of the MA is an improper criteria since third parties (such as
  universities) may have contributed to the drug development independent from the holder of
  the MA (i.e. outside of a collaboration agreement). Such third parties should be entitled to a
  SPC.
- Our answer is: none of the above, but this option was not available. We do not agree that
  case law is unclear.
- It may make more sense to require that consent in not required on making the SPC application, but is required before the application can be granted. This is because of the strict and tight deadline for applying for an SPC following patent grant or MA grant. Negotiations between multinational companies can take a number of months.
- First, we do not agree the case law is unclear. To the extent that it is unclear, it should be clarified by its author, the CJEU. Second, there should be an option "none of the above" which is different from "no opinion" as our opinion is that neither is considered adequate. It is also an issue for licence agreements, not a SPC issue.
- The question is biased. The CJEU case law is clear in that third-party marketing authorisations may serve as a basis for SPC, and this is also reflected in the office practice throughout the EU. Leaving that aside, the options presented clearly evidence a fundamental lack of understanding of dynamics. The question and the proposed answers take a static view, which is conceptually flawed from the beginning. Taking this through iterations: if the basic patent covers the product, it means that the third party does not have FTO. If the third party develops without a license, this is development at risk. If the third party places the product on the market, it risks an infringement case, which may or may not be settled by a license which would include the SPC. Hence, opting for (2) would only trigger (unnecessary) patent litigation with the third party, in order to obtain such agreement with the MAH. More importantly, this would directly go against the interest of a) research institutions and b) small and medium

enterprises, in particular biotech companies, which the Commission tries to support in innovative pharmaceutical research. It is typically those stakeholders who have done groundbreaking research, on which pre-clinical and clinical development is built. If they would be forced to obtain an agreement from the MAH (i.e. force the third party to take a license), research institutions and SME would be forced into patent litigation under the basic patent (which is a given!), just to get that consent. That would not be efficient, and highly detrimental to research by such stakeholders. Taking this analysis even further, it would be a clear invitation to the third party NOT to take out any license (not even to the basic patent): the money is in the SPC, and if the third party can avoid the SPC by avoiding an agreement, i.e. a license, they will just risk the patent litigation. In other words, changing the regulation would invite third parties to take a free ride on basic patents that clearly cover the product. That would be a completely non-sensical incentivization.

Q 56: In Europe it is not possible to obtain an SPC if the patent expires before the marketing authorisation has been granted. By contrast, in the United States it is possible to obtain a patent extension even if the patent expires before the marketing authorisation has been granted. The patent holder can in fact file an application for an interim extension before the expiration date of the patent. In practice, do you favour amending the EU Regulations in this regard?

- additional comments -
- As already mentioned I believe we should switch to a PTE system
- This amendment would cause legal uncertainty.
- It would lead to a legal uncertainty.
- 20 years shoud be sufficient time to get a MA for a patent protected product
- It would not appear necessary to question the judgement of the original legislators in setting patent expiry as a "hard" deadline for SPC filing. This is not least because in those situations where an SPC application is filed very close to patent expiry, it is likely that other, "regulatory" exclusivities (e.g. data protection of up to 10 years from MA issuance) will both: (a) serve as an absolute barrier to generic market entry; and (b) outlast any SPC protection that might be granted.
- It can be beyond the control of the patent proprietor whether he obtains the MA shortly before patent expiry or thereafter.
- That would mean the approval was given twenty years after the substance was first identified
  to have a medical use. Currently there is no Need for his due to the evergreening patents that
  are filed. This could be discussed as a feasible option, if the basic patent would be defined to
  be substance patent only, and given that the Interim Extension would be publicly viewable.
- This would create enormous legal uncertainty for third parties, which would not be sufficiently outweighed by the benefits obtained by the SPC applicant.
- There is a pending CJEU reference related to this question.
- While such may be of value, it is not a significant enough issue to warrant amendment of the Regulation.
- No because it adds further complexity and uncertainty
- I understand there is a pending CJEU referral with respect to this question. CJEU clarification will suffice.
- for reasons of legal certainty this possibility should be limited to specific conditions, e.g. to situations where the fact that at this time no MA is available should be under no responsibility of the patentee
- data protection is sufficient

- there should be clarity for third parties, the interim extension should be publised. However,
  considering that SPC last for 5 years and the data exclusivity periods are 8 years it is not clear
  which will be the benefit of granting SPCs in such situations. In the event that the MA would be
  for a new indication for an old product, the SPC should be clearly limited to the indication
  covered by such new MA and should not affect the products already on the market.
- The duration of the SPC should anyway not extend beyond five years of patent expiry.
- There is a pending EUCJ reference on this.
- But there should be exceptional circumstances that have determined a very long period of trials and the MA applicant should prove this.
- There is a pending CJEU reference related to this question
- It would generate legal uncertainty.
- Will be clarified by the CJEU.
- There is a pending CJEU reference on this issue (Merck Sharp v UK Patent Office) which looks
  at this issue for the decentralised procedure (DCP). This is a normal development of case law
  given the DCP was only introduced after the SPC Regulations came into force. The situation is
  very rare indeed and the Regulations should not be reopened for such an obscure
  circumstance.
- An SPC should be available even if the patent expires before the marketing authorisation has been granted, provided that provisions are made to ensure third party certainty.
- There is a pending CJEU reference related to this question.
- There is a pending CJEU reference related to this question.
- There is a pending CJEU reference related to this question.
- There is a pending CJEU reference related to this question.
- Wasn't aware of US provision. EU Reg is already favourable compared to US and does not require diligence in getting product into development in timely manner. You have to draw a line somewhere
- This question has been referred to the CJEU
- subject to the general concerns about any attempt to amend the regulation as previously expressed.
- this situation becomes only relevant when the development of a new medicinal or plant protection product takes a very long time or is started very late during the regular patent term, which is a rare situation; 3rd parties need certainty regarding the length of protection to be expected; balancing the very rare situations with the uncertainty that could be expected, we come to the conclusion that an interim extension, although useful in a few special situations, would not justify the disadvantages to introduce the uncertainty of predictability of protection term (this uncertainty could be limited by providing a minimum term, e.g. 6 months before regular patent expiry when at latest such an interim extension can be validly filed).
- There is a pending CJEU reference related to this question.
- The SPC Regulation provides for ample development timeline. It is perfectly possible that MA is
  not obtained within patent term in individual, rare cases. But accommodating those cases by
  an exception would only add overall complexity, which, on balance, does not seem
  warranted.

Q 57: In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself. In practice, do you favour amending the EU Regulations in this regard?

- In view of the present projects at the EPO, in the future, only very few patents will be granted only after the expiration date of the patent itself. Therefore, it does not seem to be critical amending the EU Regulations in this regard.
- It also would cause legal uncertainty.
- This has limited practical implications
- It would lead to a legal uncertainty.
- In over 30 years of practice this situation (patent grant after expiry) has never been seen
- It would create a lot of uncertainty.
- This situation is vanishingly rare and does therefore not justify an amendment to the legislation.
- Same reason as for the immediately preceding question this would create too much legal uncertainty for third parties compared to the benefits obtained by the SPC applicant.
- This question shows a lack of understanding of the patent/SPC systems. There is absolutely no
  experience of such situation where a patent would be granted after its expiration date. If
  there were, it must certainly be very limited and would therefore not justify any amendment. It
  is up to the patent owner to monitor the prosecution of its patent applications and ensure
  they are granted in time.
- This is a highly unlikely scenario, and in any case is certainly not something that needs to be addressed via amendment to the regulation.
- According to our previous answer
- we do not see this situation in reality
- We have actually achieved what is mentioned in the question as being not possible.
- This would make the situation even less predictable. What we need in Europe is clarity and predictability.
- as to the earlier question: only under exceptional circumstances
- we do not understand if the intent is to introduce the prevailing opinion in the form of a specific provision in the Regulation, or on the contrary to exclude application of this prevailing opinion. We would rather be against the possibility of obtaining a SPC in such a situation as it unduly extends third parties' insecurity
- Yes, to allow such SPCs (this question is ambiguous as to what "Yes" and "No" mean, since the EU Regulation is not currently clear on the point hence "prevailing view")
- This would increase the number of divisionals and the evergreening of patents.
- This question is really confused. I've never heard about a case where a patent was granted after the expiration date of the patent itself.
- This scenario is quite unrealistic and should as a more theoretical thought not lead to a reopening of the regulation!
- Does that situation ever occurred? If that occurred, does this exception require a amendment of an EU regulation?
- Very rare case. Applicant should speed-up prosecution in this case.
- I don't understand this question. Not aware this can happen.
- It seems that there is a problem in the question

- We have never come across this circumstance in our extensive experience of filing and prosecuting patents.
- An SPC should be available even if the patent was granted after the expiration date of the patent itself, provided that provisions are made to ensure third party certainty.
- This question shows a lack of understanding of the patent/SPC systems. There is absolutely no
  experience of such situation where a patent would be granted after its expiration date. If
  there were, it must certainly be very limited and would therefore not justify any amendment. It
  is up to the patent owner to monitor the prosecution of its patent applications and ensure
  they are granted in time.
- This question shows a lack of understanding of the patent/SPC systems. There is absolutely no
  experience of such situation where a patent would be granted after its expiration date. If
  there were, it must certainly be very limited and would therefore not justify any amendment. It
  is up to the patent owner to monitor the prosecution of its patent applications and ensure
  they are granted in time.
- The patent applicant has options to accelerate patent examination to prevent such situations.
- This question shows a lack of understanding of the patent/SPC systems. There is absolutely no
  experience of such situation where a patent would be granted after its expiration date. If
  there were, it must certainly be very limited and would therefore not justify any amendment. It
  is up to the patent owner to monitor the prosecution of its patent applications and ensure
  they are granted in time.
- Frankly, the applicant will have strong regulatory data protection period in such a situation
- not necessary because it would concern very few cases
- We have never experienced a European patent being granted after it expiration date. It must be an extremely rare occurrence, which doesn't justify an amendment.
- We would welcome amendment to clarity this point to prevent an SPC being granted in the case of a patent being granted after the expiration of the patent.
- such situations are very rare, as 20 years of pendency of a patent application is usually
  sufficient to obtain a final decision on the grant; we see therefore no advantage to introduce
  such possibility in Europe that would inherently increase uncertainty of protection term for third
  parties.
- This question shows a lack of understanding of the patent/SPC systems. There is absolutely no
  experience of such situation where a patent would be granted after its expiration date. If
  there were, it must certainly be very limited and would therefore not justify any amendment. It
  is up to the patent owner to monitor the prosecution of its patent applications and ensure
  they are granted in time.
- The SPC Regulation provides for ample time to obtain the SPC. It is perfectly possible that the basic patent is granted only after expiration of such patent, though those are are cases. Accommodating those cases by an exception would only add overall complexity, which, on balance, does not seem warranted.

# Q 62: In your experience as an SPC applicant, are there aspects of the national granting procedures that constitute a burden for applicants, and where harmonisation would make sense?

- The granting procedures do not have the same requirements from one country to another. The interpretation of regulation also differs.
- There are several aspects: 1) Since the case law of the CJEU is still interpreted in a different way by the national Patent Offices, the type of SPCs, which are finally granted for the same product may differ significantly throughout Europe. Here, a Unitary SPC may help. 2)

Currently, in many cases a large number of SPC application is filed for the same product at the same date in a large number of EU member states. However, unfortunately, some Patent Offices suffer from enormous backlogs. As a result thereof, in some EU member states, SPCs are granted very rapidly, whereas in particular in the UK and in Germany, in some cases SPCs are only granted shortly before expiry of the basic patent. Therefore, with respect to the SPC fillings across Europe, it would be favorable, if there would be deadline for the Patent Offices to starting examination of the SPC applications, e.g. at the latest 3 years after the filing date of the SPC application. In an ideal world, the parallel SPC applications would be examined simultaneously across Europe.

- the time factor is a burden all patent offices should be required to grant (or deny) SPC applications within 12 months from filing
- The application for a paediatric extension requires excessive documentation, and could certainly be simplified
- see question and answers before
- There are a lot of differences between the patent offices in how they approach the case law of the CJEU in processing SPC applications which can lead to different outcomes. There is a different understanding what is "Basis patent", "1st Registration", "product", "date of the 1st Authorisation. There are also differences between general admininstrative procedural rules in EU member states that can lead to different outcomes on the same application.
- retroactive effect of withdrawal of an SPC application is unclear CJEU case law is very often unclear
- The discrepancies between National patent offices are in my experience very minor. They could be improved by new guidelines rather than by any amendment to the Regulation.
- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, while national granting procedures are already largely similar and we see no need for harmonisation, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- No
- The speed of handling SPC applications differs greatly: in some countries the authorities only take weeks to come to a decision (not) to grant, in others the authorities wait until the basic patent is about to expire. This brings protracted legal uncertainty for all parties. Further a single granting procedure, resulting in a unitary SPC, would be supported. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- National granting procedures run in parallel. A practical improvement could be a central repository for the applicant and national offices where common documents could be stored that are needed in the different national granting procedures.
- there are in my experience no substantial difficulies
- Decisions of the CJEU should be immediately included in the day to day guideline for examination and interpretation of the SPC regulation, and not be at the National Office discretion whether to apply them or not. Harmonization should be total to favour legal certainty
- Unclear case law is the greatest burden for SPC applicants
- Harmonisation on calculation of SPC term (though this would in part require harmonisation of patent terms).

- We think that national granting procedures are similar. Further harmonizations are not necessary.
- The granting procedure is not burdensome when we have a central approval.
- The main problem at the moment is the lacking guidance given by the CJEU and, as a result, the different interpretation of the CJEU case law by the national offices.
- There are many differences between the patent offices but especially between the rules of
  procedures in the EU member states. Therefore, a single centralized granting procedure,
  resulting in a unitary SPC, would be highly welcomed for harmonization purposes and to
  prevent a fragmentation of the internal market.
- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- No
- The burden with respect to national granting procedures is only that an applicant must do so many and all at once. National granting procedures are generally similar, but a single granting procedure, resulting in a single SPC with effect throughout the EU, would both simplify the process for applicants and provide clarity for those seeking to determine whether or not a particular European patent has been extended by SPC. Even without a "Unitary SPC," processes could be implemented to simplify both the application and grant processes for SPCs. For example, a single repository could be created for access by applicants and patent offices into which the application, supporting documents and even guidelines for substantive review of applications could be deposited; thereby simplifying and likely expediting the request/grant process.
- Surely, a centralized SPC application procedure would be the best way to proceed in order to grant harmonization.
- Some small differences exist but in our experience these have not caused any undue difficulties.
- The main problem is the different interpretation of the regulation and the CJEU decisions. For example, different interpretation whether it is possible to rectify the SPC term, whether mixtures of active ingredients are entitled to their own SPCs from the AI patent, etcetera
- There is no particular burden.
- There are no specific aspects of national granting procedures constituting a burden for applicants other than the high number of parallel granting procedures that a company has to go through to apply for SPCs throughout the member states. While national granting procedures are already largely similar and harmonized, so that I see no further Need for harmonization on a national Level, a single granting procedure, resulting in a unitary SPC might be welcome. To make the logistics easier when applying for national SPCs, creating a central repository for documents, which are necessary for all national granting procedures, would be practical, so that they would Need to be filed by the applicant only once with the central repository, from where they would be accessible by national Offices there.
- There are no specific burdens.
- Yes.
- 1. the question of amendments after filing the SPC application substantially differs between national offices; in some countries national provision exist which exclude any amendment.

  2. The product definition is very different on national label.

  3. The extend of examining Art. 3a widely differs; in particular in cases of use patents, i.e. are features like "synergistic effect" of a combination of active ingredients in a claim fulfilled in the product of the MA

- For pediatric extensions where the non-centralized is used there is a lot of work Not a huge burden to file but it should be possible for the PTOs to obtain MA documents themselves such as products summary etc.
- The French patent office requires that subject matter for which protection is sought be specified in the SPC application. This is not required everywhere and raises issues as to the SPC scope. The French law provides that the SPC is automatically deemed to be refused if the SPC is not issued within 12 months from filing. This raises issues for the SPC applicants that wish/need to delay grant of the SPC, for instance if the basic patent is undergoing opposition proceedings. When the basic patent is revoked, there should be a simplified/rapid proceeding available in all countries to declare nullity of the SPC.
- sometimes lack of training of the examiners
- No. As long as the individual countries are not harmonised with respect to the original patent filings a qualified response per country provides the necessary flexibility.
- Different interpretations of article 3. Implement an attitude of allowing not rejecting applications.
- Regarding the previous question of amendment of the product definition. There should be no definition of the product in the SPC application, because there is no basis for that in the Regulation and there is no need for it. The scope of protection is provided by Article 4, and not by any product definition. Thus, there is no need for a provision for amendment. Also, the practice of national patent offices to allow product definitions, without any legal basis, is a burden for applicants.
- National granting procédures are burdensome because they are national and therefore the applicant needs to prosecute many SPC applications in parallel. A unitary SPC would be a good way to simplify procédures for applicants.
- Yes, for example national specific examination standards and high variation in examination timelines. Harmonisation makes a lot of sense, maybe through general mandatory guidelines for examiners.
- In Italy the application procedure does not really present any particular burden
- this is not a direct answer, but the disparaty in examination is a serious issue. in UK, DE, ES, SE, NL and FR there seems to be serious examination but elsewhere there is non.
- The fact that a company has to go through a high number of parallel granting procedures is quite a disadvantage. Therefore, while national granting procedures are already largely similar and we see no need for harmonisation, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material
- Yes, including: Differences in applying the "Medeva test" for whether a product is protected by the basic patent, from offices applying what is almost the "infringement test" to offices that require verbatim claim language for the product. Differences in administrative law, such that some countries will retroactively correct grant decisions with respect e.g. to duration (cf Seattle Genetics) and some will not. Also, different countries calculate the term differently, so that it may differ by one day dependent on whether the first day of the SPC term is the day of the patent expiry or the day after. Differences in formal requirements, e.g. power of attorney, originals/scanned copies etc. It would be preferable if these requirements could be made as simple as possible
- National rules set further substantive requirements (eg inBulgaria, Hungary) that suggest harmonization of procedural aspects is needed
- The mere existence of many authorities to grant SPCs is a burden.
- French IP code provides that an SPC must granted within one year from its filing date, unless objections are raised. If not it is deemed rejected. This makes the grand proceedings of SPC in France difficult and unecessarily risky.

- Maybe a centralized SPC granting procedure, at least for a centralized EMA approvals.
- Requirements for the wording of the "product" in the SPC application
- e.g. how you may define the product for which protection is sought. It appears to differ between countries.
- The speed in handling SPC applications differs greatly from state to state. A uniform method for handling such applications would be greatly desired.
- you have to go through multiple granting procedures with different time lines and sometimes different outcomes. A centralization would be favorable
- We do not have experience as an SPC applicant, but all stakeholders would benefit from a more rigid, defined and relatively short timeframe for the national SPC granting procedures.
- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, while national granting procedures are already largely similar and we see no need for harmonisation, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- No
- Definition of the product object of the SPC: In some countries, like France, there is no "definition" of the product object of the SPC, but the product is only referred to by the INN as it is in the MA.
- A central repository of documents needed to support an application could be hosted on the
  internet between the national patent offices. This would avoid duplication in submitting
  applications. If this question is asking about substantive examination procedures then
  harmonised guidelines common to national offices would lead to smoother processing.
- From an experienced applicant's perspective, there are no specific aspects of national granting procedures that constitute an undue burden. A very practical improvement could be a central repository accessible by applicants and national patent offices containing the details of common application documents to avoid duplicative filings of these documents. In as much as this question refers to harmonisation of substantive issues being considered during the granting procedures, we would welcome if the Commission issues guidelines on the interpretation of the CJEU case law to help consistent interpretation by patent offices.
- Yes. Stays should be made more widely available and uniformly granted. The speed of examination should also be harmonised to improve legal certainty.
- There are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. A single granting procedure, resulting in a unitary SPC, would be welcome as long as the introduction of a unitary SPC does not result in the modification of the current SPC Regulation
- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, while national granting procedures are already largely similar and we see no need for harmonization, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorization, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.

- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, while national granting procedures are already largely similar and we see no need for harmonisation, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- In case of a centralized marketing authorization procedure the burden is limited to apply at
  each national Patent Office on basis of the same information. Most of the national granting
  procedures themselves are comparable. Common guidelines may be benefician as well as a
  common SPC register. For the unitary SPC one process for application and grant will be of
  advantage.
- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, while national granting procedures are already largely similar and we see no need for harmonisation, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- There are quite a few countries who either can't examine (because the IPO lacks expertise) or examine poorly (because they do not have the expertise). Frankly, I rely on the UK, Germany and the Netherlands.
- Yes in relation to the access of staying proceedings if the basic patent is subject to an EPO opposition or if an opposition of a basic patent otherwise relevant to a pending SPC application is initiated Yes in requesting prioritised examination of one application over another when two or more applications from the same applicant regarding similar products are pending Yes in requesting extension of time limits for responding to Office Actions Yes in staying proceedings awaiting the outcome of questions pending before the CJEU that are of relevance to the application
- It sometimes takes years to get a first office action. Given the importance of SPCs, a case
  management system should be installed, for instance 6 months to 1st office action, then 4
  months reply deadline, and 4 month window for next office action/allowance.
- Although the current national granting procedures are highly similar, it would be preferable with a single granting procedure resulting in a unitary SPC.
- Multiple different requirements results in huge burden for applicants
- Yes, in the interpretation of Article 3 (a) EPC. EU-wide harmonization of this interpretation
  would help greatly, as would a dedicated definition in the SPC Regulation itself.
- From an applicant's perspective, there are no specific aspects of national granting procedures that constitute a burden for applicants, aside the fact that a company has to go through a high number of parallel granting procedures. Therefore, while national granting procedures are already largely similar and we see no need for harmonisation, a single granting procedure, resulting in a unitary SPC, would be welcome. A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices.
- No. The national granting procedures are overall very efficient.

Q 67: The introduction of a "SPC manufacturing waiver" for the export of SPC-protected active ingredients to patent- free markets is currently being considered. This would allow generic companies to manufacture SPC-protected drugs in Europe for export to patent-free countries without infringing the SPC rights. By manufacturing we understand "manufacturing of a final product", and not packaging. What do you think of the idea of introducing such an "SPC waiver"?

- The healthcare sector is a patent-intensive sector and it is expected that SPC protection will remain a critical incentive for healthcare innovation. opposes the introduction of an export manufacturing exemption because: (i) it would not generate any material overall economic benefits in the European Union, (ii) it is likely to undermine the integrity of an important intellectual property right for the healthcare sector, and (iii) it could be detrimental to the development of future innovative (bio)pharmaceuticals in Europe and globally.
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), we strongly oppose proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing – substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, it it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledgebased economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?
- good idea
- great idea
- Good idea.
- An SPC waiver would be contradictory to the SPC Regulations. European generic companies may also produce SPC-protected drugs in patent-free European or in non-European countries.
- The question is not clear as it is not understood what is meant by "manufacturing of a final product" and not packaging. However, we oppose any type of SPC manufacturing waiver.
- it will make the system even more complex eg how can you make sure that all batches manufactured will actually be exported to patent-free countries?
- There is an urgent need for this in order to prevent generic and biosimilar production sites from
  moving to non\_EU countries. An SPC manufacturing waiver could allow the European generic
  and biosimilar medicines industries to create thousands of high-tech jobs in the EU and many
  new companies.

An SPC manufacturing waiver is extremely needed. The SPC Regulation, as widely recognised, has the unintended consequence of forcing generic and biosimilar medicines production to non-EU countries where no similar protection is in place. This puts the EU industry at disadvantage vis-a-vis non-EU competitors. This situation prejudices competitiveness of EU companies in the in key export markets, like for instance the US market, where patents and patent extensions will, in most cases, expire earlier than in the EU due to the more rapid introduction of new medicines. This is the case with major biological products as well as chemical molecule products. In addition, this situation gives an unintended lead time advantage to non-EU based operators as regards entering EU Member States generics market immediately upon the SPC protection expiry. An SPC Manufacturing Waiver would fix these unintended side effects of the SPC by allowing generic and biosimilar medicines developers to produce during the SPC period in order to supply unprotected markets as soon as possible. In no will it undermine or change the existing IPR equilibrium in the EU. An SPC manufacturing waiver will bring high skill pharmaceutical R&D and manufacturing back into the EU (companies always prefer proximity of research centers to the manufacturing of the product, so it will actually increase R&D in Europe). It will develop and strengthen EU manufacturing science, boost European SMEs, strongly support the European Active Pharmaceutical Ingredients (API) industry, increase the EU trade balance, create economic growth in Europe and ultimately boost the opportunity for the European industry to compete for global leadership. There is no risk with a manufacturing waiver that generics and biosimilars enter the market before SPCs expire. The rules in place today to avoid that this happens will not change at all with an SPC MW. EU countries have all the necessary legal tools to block and seize infringing pharmaceuticals before they reach the market (e.g. preliminary injunctions), and this will not change. NB. until very recently, in eastern European countries, where SPCs where not in place yet, there were already on the market generic products that were unprotected in those markets but still protected in Western EU markets. This did not create infringement issues in protected markets, therefore an SPC manufacturing waiver would not create any specific risks. The SPC MW is only about entering the market and creating competition immediately after SPCs expire. European companies today cannot do it. Either they produce abroad, or they enter the EU market over 6 months after SPCs expire. The SPC manufacturing waiver is not about competitiveness between originators vs. generics. It is about competitiveness between European vs. non-European pharmaceutical industries.

### Good idea

While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), strongly opposes proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing – substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledgebased economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?

- It would weaken Europe's IP System. A region like Europe with high labor costs and high environmental standards is unlikely to compete with countries with low standars in IP protection. The SPC waiver is unlikely to have Overall an Advantage to Europe
- Might help industry but for the patent/SPC owner it would be a big disadvantage as he/she
  would need to control the production and that it is only used for export currently which is
  combined with high expanses. In the sense of patent law this would take all use from a SPC.
- SPCs are created to stimulate investments into R&D. SPCs should provide the same scope of
  protection as the basic patent confers. Introducing a manufacturing SPC waiver would
  fundamentally undermine this right. Would be detrimental to development of further
  innovative products in the EU.
- I think it would open the door to more legal uncertainty for SPC holders. Focus should be on convincing patent-free countries to amend their laws to install a fair system that actually stimulates innovation for health, rather than to just rely on the efforts of other, more developed, countries.
- In general benefit for EU: Generic industry can produce in Europe and can generate jobs in the EU.
- has several concerns about the proposed introduction of an SPC manufacturing waiver as it may undermine the SPC regime while not achieving the desired objectives. Even if it is a sui generis protection per se, the SPC confers a patent-type protection which includes protection against manufacturing. Moreover, this could encourage other countries in the world to follow a similar approach. If countries that currently respect extended patent rights were to implement a similar waiver, this would end up undermining the value of patent protection as such, which would send a bad signal for innovators and their investors. Another concern relates to the enforcement of such a measure. It seems difficult to provide an absolute guarantee that generic products are manufactured in the EU only for export in countries where the protection has expired or doesn't exist at all. There may be situations where products are exported to countries where companies may benefit from potential IP rights not yet granted due to a deficient IP system or simply in countries where generic manufacturers decide to challenge a patent and launch the generic product anyhow. Such provisions would make it harder for right holders to enforce their rights and weak judicial redress systems in export markets may act as an additional obstacle. By introducing an SPC manufacturing waiver, the EU IP regime would therefore be weakened with the primary objective of encouraging local generic manufacturing. However, it seems unlikely that the manufacturing waiver will effectively attract more manufacturing in the EU. There are various considerations that underpin decisions on the location of manufacturing, which includes costs but also quality and reliability of supply, as well as local market access conditions. Regarding the later, in fact, many of the export countries currently favour local generic manufacturing, meaning that the market opportunity for EU-based generic manufacturers is relatively low. Moreover, evidence suggests that quite often, the window of opportunity for EU-based generic manufacturers is relatively short as IP doesn't expire significantly earlier in non-EU markets compared to EU markets. Considering this and the fact that manufacturing in the EU may sometimes be associated with higher costs than outside the EU, the positive effect on EU manufacturing and job creation is uncertain.
- Bad idea
- Like the existing systems the generics will test the gray areas (stock piling for sale after EP
  patent lapse etc.). It will will be too complex in my opinion
- is definitely in favour of this to protect the EU manufacturers and jobs in EU
- worth exploring further
- I am unaware of any persuasive evidence that the existence of an SPC right has an
  economic impact on the ability of European generics to compete in this situation. I am
  concerned that introducing a waiver risks significant and unintended economic
  consequences.
- It makes sense. There is no prejudice for the Originator in this case.
- Could help European generic manufacturers to survive

- We do not support the idea of introducing a manufacturing waiver, and agree with EFPIA's comments in response to this question.
- This would constitute a violation of current patent law application in Europe, which should be avoided.
- SPC are created to stimulate investments in further R&D. SPC should provide the same scope of protection as the basic patent confers. The introduction of an SPC Manufacturing Waiver would be detrimental to the development of future innovative pharmaceuticals and crop protection products in Europe and globally. Furthermore it would be a negative signal about EU's respect for and seriousness about building a knowledge-based economy if SPC as a kind of IP protection will not be respected.
   Additionally, it would be inconsistent with EU's trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective.
   The potential of such a measure to bring more highly-skills jobs back to Europe, as argued by the generic industry, is highly contested because of reducing demands of originator products leads to highly-skilled job losses in the branded sector at the same time (see analysis by Sussell et al., Journal of Generic Medicines 2017).
   The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. It is to be questioned whether this is the main factor and whether there are actual opportunities given the existing competition dynamics within key export markets.
   Contrary to generic industry claims, introducing a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It further deprives originators of potential licence revenues, had they licence out the right to manufacture for exports.
- We don't think it is appropriate to treat SPC protection any differently from basic patent protection and there should be no waiver.
- We strongly oppose proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledge-based economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production.
- Strongly in favor of an SPC waiver & packaging should be included.
- We oppose to this idea. The healthcare biotechnology sector is a patent-intensive sector and it is expected that SPC protection will remain a critical incentive for healthcare innovation. opposes the introduction of an export manufacturing exemption because: (i) it would not generate any overall economic benefits in the European Union, (ii) it is both likely to undermine the integrity of an important intellectual property right for the healthcare biotechnology sector, and (iii) it would be detrimental to the development of future innovative biopharmaceuticals in Europe and globally.

- Is very important for the European Pharma Industrie and will bring new jobs
- We do not support such an idea. It could have an impact on European originator's export to
  these markets. It will also have an impact on European originators in terms of monitoring /
  enforcement whether such idea would be limited to its intended purpose. Further we are
  concerned that implementation of such idea may ultimately lead to introduction of such
  "waivers" in patent systems of other countries.
- I am not in favour since this narrows the protection provided by the SPC to less than the patent laws give as patent protection (covers the maufacturing) and is not justified since even if generics produce in patent free countries they cannot import to the EU if it is patent protected there. The fact that they go somewhere else must be tackled by other measures.
- In favor
- This may be usefull to ensure local manufactrure
- Could be part of the solution, taking into account that there is no loss for the patentee since
  the generic product will not enter the EU market before expiry of the SPC. This will also
  eliminate the de facto extension of the monopoly (time for manufacturing the generic
  product in EU for EU market)
- It may be a positive idea, as it may allow smaller pharmaceutical companies to center its core bussiness in producing "not-burdened" substances for third countries.
- Currently we are manufacturing only outside EU.
- An SPC manufacturing waiver is strongly needed and will support generic companies in the decision to keep up production in Europe. It will by no means change the IPR rights for the originators. His economic monopoly as intended by patent/SPC protection is in no way touched. As one can see all over the markets today generic products are on the market the next day after patent expiry. At the moment these products necessarily come from production sites from countries without Patent/SPC protection but they come. The only change after introducing a manufacturing waiver will be that these products at day 1 on the market after patent expiry must not necessarily come from production sites outside the EU but could come from EU-sites. The economical situation of the originator which is intended to be protected by patent/SPC is not at all touched by this: In one case the generic product comes from outside EU, in the other case it comes from inside the EU but they both come on the same day which is day 1 after patent expiry. Thus the competition is not between originator and generic but only between generics from inside and from outside the EU. The manufacturing waiver would also not trigger any SPC infringement. Historically the location of a production might have had an impact on the economical situation of the patent holder: If the production site was in the country it would be easier for the infringer to exploit the patent economically because the product was available on the market. For this reason patent protection was extended to the production phase. But this concept does not play a role any more as the logistic chain is good enough to deliver any given product to any given market at any given time from anywhere in the world. It can be stated that in markets like in Germany there hasn't been any generic product on the market before patent expiry for many years. The reason for this is not that the product could not be imported or otherwise being brought to Germany but is mainly because any action to get into a reimbursement scheme (i.e. the necessary listing in the reimbursement lists) would have immediate legal consequences as patent infringement (independent of the question where the actual generic product is coming from). Without being in a reimbursement scheme it doesn't make any sense to try to sell products. As there is no manufacturing waiver the generic companies are forced to start the generic production outside the EU. If they have started the production there it is very likely that they will continue to manufacture outside because any relocation of pharmaceutical production is costly and complicated due to the many regulation on pharma production. Additionally it shows in the last years that increasingly not only the generic production moves outside EU but also the generic research and development in new generic substances as it is easier if development and production are at the same place. A manufacturing waiver would therefore strengthen the competitivness of EU production, it will hold back in the EU high skilled pharmaceutical R&D as well as production, also the production of Active Pharmaceutical Ingredients, and thus not only create economical growth in EU but also reduce the heavy dependency of Europe from Non-Europe-countries.
- OK with it.

- no
- We strongly favour the SPC waiver, in the sense it defines an exclusion from SPC protection for the purpose of export and manufacture during SPC period for domestic launch after SPC expiry.
- It is essential in order to not degrade the capability of the EU and the UK to manufacture its own medicines. This is a strategic industry. It is fundamental. In the event of a major international incident do we want to be reliant upon non-EU countries for manufacture of all essential medicines? NO.It affects two markets generic medicines where asymmetric protection means that to launch across the EU on day 1 you have to import the product from a non-EU source. There is no degrading of the SPC holders commercial rights as day 1 will happen in any event regardless of the source. The second area is the emerging market in biosimilars. The EU will not establish a successful manufacturing bases if it cant manufacture for its own domestic market. Finally it is a well known principle that all successful international business start from a strong domestic base. The SPC regulation prevents a strong domestic base from being formed for manufacture of generic medicines or biosimilars
- I would question whether such a waiver represents a "limited" exception that could be permitted under Article 30 of TRIPS.
- We strongly disagree and oppose the proposal. We don't think that such proposal lead major
  economic positive impact. On the other hand, we are afraid of serious negative impact on
  the originators.
- We agree with EFPIA's position on this issue.
- good idea
- totally agree!
- In principle, we are not against the idea of such a waiver. But it needs to be ensured that the manufacturing does not serve the purpose of early entry in the EU market.
- SPCs are created to stimulate investments into R&D. SPCs should provide the same scope of
  protection as the basic patent confers. Introducing a manufacturing SPC waiver would
  fundamentally undermine this right. Would be detrimental to development of further
  innovative products in the EU.
- An spc waiver will be more than welcome in our company. Nowadays we are looking for facilities outside Europe in order to manufacture products that we would like to sell in countries with no patent limitations that in europe are still protected
- Proposals to introduce a SPC manufacturing exemption for export should be opposed. It would be a negative signal about EU's respect for and seriousness about building a knowledge-based economy if SPC as a kind of IP protection will not be respected. Additionally, it would be inconsistent with EU's trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. - The potential of such a measure to bring more highly-skills jobs back to Europe, as argued by the generic industry, is highly contested because of reducing demands of originator products leads to highly-skilled job losses in the branded sector at the same time (see analysis by Sussell et al., Journal of Generic Medicines 2017). - The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. It is to be questioned whether this is the main factor and whether there are actual opportunities given the existing competition dynamics within key export markets. - Contrary to generic industry claims, introducing a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It further deprives originators of potential licence revenues, had they licence out the right to manufacture for exports.
- It may be a good idea. It has been implemented for example in Italy in a particular situation.

- I am very much in favour of a SPC manufacturing waiver. The SPC Regulation forces generic and biosimilar medicines production to non-EU countries where no similar protection is in place. This puts the EU industry at disadvantage vis-a-vis non-EU competitors. This situation prejudices competitiveness of EU companies in the in key export markets, like for instance the US market, where patents and patent extensions will, in most cases, expire earlier than in the EU due to the more rapid introduction of new medicines. This is the case with major biological products as well as chemical molecule products. To not lose out on business and employment opportunities for European API Producers and pharmaceutical product manufacturers to deliver into the rest of the world, while others can supply the markets freely, such as US where the protection runs out earlier. It is also important to be able to deliver into the European markets at day 1 after patent expirity, this is only possible with a SPC manufacturing waiver. Another Advantage of keeping production in Europe is, that here the environmental regulation is much more effective and so the production will be less harmful for the environment. Which goes hand in hand with the current sustainability goals of the EU and the UN.
- I am against the idea and fear it would lead to a decline in European innovation
- It would surely be of great benefit to the generic industry but would strikingly go against an established principle of patent law of virtually all EU member states, i.e. that manufacturing the invention in a country where the invention is protected by the patent is an infringement regardless of what the manufacturer then does with the manufactured product (e.g. stores it until patent expiry, exports it, etc.)
- While the wording of this question refers alternatively to active ingredients and final products strongly opposes proposals and does not define "final products" (these are different), strongly opposes proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing – substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledgebased economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?
- An "SPC waiver" should not be introduced
- We think such a "manufacturing waiver" is inappropriate, unnecessary and counterproductive. The purpose of the SPC is to compensate the innovator for patent term lost due to the lengthy (and expensive) development and regulatory approval processes. Even given this fact, no more than 5 years of patent term can be restored, regardless of whether more than five years have been lost. (See, e.g., Sussell et al., Journal of Generic Medicines 2017.) Either patent rights are valuable and the goal of incentivizing investment in innovation, despite the lengthy and expensive regulatory process, is valuable or they are not. There is ample evidence that generic companies suffer little to no economic harm because of SPCs. Whereas, the erosion of an intellectual property right harms EU innovators not only by virtue of the value of that right in the EU but also by setting a precedent for other countries to rely on to also erode innovator's IP rights. Additionally, such a waiver would result in erosion of innovator

exports to the "patent free" country, and substitution of lower value generic sales for higher value innovator sales will result in a net loss to the EU economy. Finally, such a "waiver" would, to be fair at all, require protections to be created to prevent, detect and stop abuse of the waiver. Who will ensure that the generic company is only making enough product to export and is only exporting to countries where the innovator has NO patent protection for that product (or it's labeled indication or formulation or dosing regimen or etc., etc.)? How will one detect a violation, and what remedies will be available to the patent holder? Injunction? Damages? Loss of right to manufacture under the waiver? And what legal infrastructure will be required to be put in place to protect the innovator's right in its intellectual property?

- We are strongly against this idea.
- I do not support the introduction of such a waiver. Many factors influence whether legitimate generic manufacturing may occur in one country or another. There is no reason to single out SPCs and to do so would unjustly erode the benefit of the SPC to the developer and set a terrible precedent for the EUs regard for IP rights.
- very positive
- In favour
- In the plant protection area it is not necessary.
- We strongly disagree with such an SPC waiver.
- While the wording of this question (and therewith the scope of the intended waiver) is not
  entirely clear once referring to SPC protected active ingredients and then referring to SPCprotected drugs (not closer defined), the introduction of such a waiver altogether is strongly
  objected to.
- Studies on the benefit of a SPC waiver to EU companies came out with divergent results. Since there is no clear evidence for an advantage, the SPC waiver should not be implement as it would represent an erosion of existing IP rights.
- It would be a positive and reasonable provision.
- On the whole our clients do not support such a manufacturing waiver
- Not always necessary, as there is not always an SPC in every EU country. So in some EU
  countries the product could still be manufactured right after patent expiry.
- in my point of view this could be a reasonable and appropriate exemption.
- In its current formulation the document is much broader than indicated above e.g. including biosimilars. In addition I wonder why this waiver shoul only apply to pharma products and not all products (if it should be introduced at all)? It would be a bias against pharma industry over other industries. Allowing this would necessarily give these manufacturing entities an advantage also in Europe when SPCs expire since they would be all set so it will change the current competitive landscape and this should be kept in mind. Who will make the huge investments in new developments in the future if the ROI is mitigated.
- we would be favorable but the "SPC manufacturing waiver" should not authorise the generic company to constitute stocks for immediate commercialisation in Europe when the SPC expires.
- This is a bad idea. It removes a significant part of the value of an SPC which, like a patent, gives the exclusive right to manufacture. Exactly the same argument could be made for a "patent waiver" for export to countries where there is no patent, perhaps because the patentee did not pursue protection, during the term of the patent. Efforts should be focused on trade commitments to improve protection in third countries rather than reducing protection in the EU.
- We are against it. SPCs are not a driver for companies to decide where to locate their
  production, the cost of production is rather the primary criteria for any company (be it
  generic or not). This would be particularly true for the EU, where production costs are more
  likely to be higher, and would rather deter companies to locate their production there.
  Moreover, the "SPC manufacturing waiver" is likely to create an opportunity to stockpile their
  production until patent or SPC expiry.

- I am for introduction of a SPC waiver.
- Dangerous, stocking and use for the European market may occur
- Mixed feelings because under WTO rules preparatory work to get the marketing authorization is not considered a patent infringement, stock piling however is an infringement. The SPC manufacturing waiver may be considered as stockpiling.
- unacceptable
- I oppose that idea as it undermines the Basic principles of patent protection.
- Great idea. This would strengthen the European generic industry and remove the competitive drawback against the manufacturers of other countries especially China and India.
- Would not secure the investments of innovators
- believes that an SPC manufacturing waiver could allow generic manufacturers to create new jobs in both scientific and technical areas while ensuring the supply of the market with quality pharmaceutical products. Specifically in Greece, an SPC waiver would encourage future investment of companies to increase exports of domestically (and thus European) produced products, create new jobs, boost SME businesses and cultivate an extraverted mentality directed to high quality and efficient products. generic manufacturers will be able to take advantage of the EC's proposed supplementary protection certificate waiver, the effect of which will be to increase R&D expertise and support the national economy. However it is unclear what is being suggested as "manufacturing of a final product" excluding or not including packaging. This would highly undermine the ability to export products which need special handling with regards to external weather and other factors. Furthermore, it has never been defined as to what packaging refers to primary or secondary packaging? An SPC waiver would not have the same effect if in practice a product or company is unable to export because the specific product is in semifinished form and cannot be exported without packaging.
- Good idea
- This would reinforce European generic producers.
- good idea
- In favour, It would be good for the European Economy.
- I don't like it.
- Good idea
- The SPC waiver would increase the availability for european based manufacturers to compete in similar conditions with companies based in countries with no extensions.
- Bad idea goes against the fundamentals of IP rights.
- The EU rules on patent exemption for emergency situations should suffice for business purposes. Pushing manufacturing out of the EU encourages build-up of manufacturing competence outside EU, which is generally good. However, chemical manufacturing in third world countries is often quite polluting, so pushing manufacturing outside the EU could lead to increased pollution. That should be countered by active support of tech transfer in areas of clean chemical manufacturing on an EU level. A little bit off-topic as relates to SPCs, perhaps...
- I think that this seriously undermines the established patent system and is unjustifiably unfair to patentees. The generics can still manufacture the product, but outside the EU. There is insufficient evidence to support a "business case" in terms of benefits to the EU by way of jobs, revenue, etc that would justify this approach.
- A manufacturing waiver would undermine the fundamental principle of the SPC (incentivizing research and development by compensating for regulatory delay). It would also send an adverse signal to countries with weak patent protection.

- This is a highly sensitive topic, and rightly so as it would significantly erode the rights of SPCs holder and introduce considerable issues in respect of adequately policing this issue. If considered at all, it should be very carefully considered and examined in a broader context looking at incentives and regulatory rights generally.
- I would oppose the introduction of an SPC manufacturing exemption.
- Broadly in favour
- An SPC manufacturing waiver might be very interesting and could foster further the
  pharmaceutical industry. However, it would also provide those companies with a certain
  advantage for launching the product in Europe once the SPC expires. Hence, a wellfunctioning control system would be required in order to assure that only product is launched
  in Europe that has been manufactured after the expiry of the SPC.
- An SPC manufacturing waiver is extremely needed.
- A SPC manufacturing waiver is not necessary. The Party that needs a waiver or is in favour
  thereof can always contact the SPC-holder for a license on an arms length basis. The right to
  be active in a country with SPC protection can not be provided on a royalty free basis and
  anyhow would require a compensation payment. Therefore, it should be left to the involved
  parties to negotiate this license rather than providing such a waiver via some legal measure.
- Do not agree unless agreement between the patent holder and the generic
- The waiver could be allowed only for cases in which the originator does NOT produce the active ingredient in Europe.
- Great idea, should also be extended to packaging and stockpiling
- this would allow the EU to compete with the rest of the world as at the moment there is a significant delay between the EU and (eg) the US that causes uncertainty with cost and looking for CDOs and CMOs in other countries.
- We strongly oppose to a proposal to introduce a SPC manufacturing exemption for export. It would be sending a very bad signal about EU's respect for and seriousness about building a knowledge-based economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?
- I disagree. Monitoring and enforcing in order to make sure that such manufactured products
  would only be put on the intended patent-free markets, not the EU market in which they were
  produced, would be an undue and serious burden upon the research companies.
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), strongly opposes proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all,

to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledge-based economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?

- This would hugely increase legal uncertainty!!!
- We support Efpias comments
- First, packaging is part of manufacturing and should not be excluded (another thing is stockpilling before patent expiry). This measure will not damage innovative industry at all, as there are many manufacturers working out of the EU that will not be stopped. This measure will provide equal opportunities to the generic industry based in Europe. This will allow to retain high-value workers and technology in Europe and be competitive as manufacturers, without allowing the sale of protected products before SPC expiration. I find that there is no valid justification not to allow early manufacturing for third-countries.
- Good idea to avoid that all manufacturing activities go to other countries.
- Not a good idea. Suggested benefits would be highly limited.
- Personally I have serious doubts about Generic companies manufacturing in Europe to export in countries in which there is no SPC and therefore already generic competition. Indeed, most of such generic companies have invested outside Europe (to competitive with Chinese and Indian API manufacturers for markets outside Europe) or do already buy the API from companies located outside Europe at reduced costs. I have doubts that companies producing API in Europe would bring competitive API (lower price) versus local production in India or China for markets outside Europe/US. Finally, for several small EU member states or for new EU member states there were/are no patent protection at all for many, many drugs and these patent gaps did never stimulate European generic companies to actively produce in these countries to export outside the EU. A lot of American/Japanese companies or start-up companies do not patent protect their products in all the EU member states. For instance our company commercializes a patent protected drug which has no patent protection in e.g. Poland etc, and no European generic company has ever produced our API in Poland etc. So the SPC waiver rational is based on pure speculation which has never been confirmed by proper facts and business cases.
- We are totally agree with the introduction of the SPC waiver because we think that the
  legislation must be allow the fine Chemical Industry to manufacture, prepare, supply and sell
  active pharmaceutical ingredients covered by a Supplementary Protection Certificate before
  the expiry of that right, provided the active pharmaceutical ingredients is exported or used to
  manufacture medicines that will be exported to countries out of the European Union where
  there is no patent and/or where it has expired
- We strongly disagree. First, this undermindes the patent/SPC protection. Second, it will be very
  difficult, time-consuming and burdensome to control these types of waivers for the patentee.
- Significantly oppose any proposal to introduce a SPC manufacturing exemption for export.
- It is a good idea and should not be contentious.
- We would be against such a waiver
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), strongly opposes proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of

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- We do not agree with this idea
- As Europe positions itself globally as an innovation intensive economy, dilution of IP rights in
  favour of generic industries would send a very negative signal on industrial policy. Our
  company has a very significant manufacturing presence in the EU producing high value
  finished products for export around the world. Introducing a waiver of this type would
  inevitably impact our investment in this area and lead to job reductions. We cannot believe
  these negative economic consequences would be outweighed by job creation in generic
  industries.
- Sounds reasonable. But is the patent situation really the driver for decisions on where certain products are to be manufactured? It would seem that total cost of manufacturing are decisive, and Europe has already somehow lost the role as "pharmacy for the world".
- an SPC manufacturing waiver should not be possible
- If such a manufacturing waiver was introduced, there would need to be significant
  safeguards to ensure its proper use to avoid it becoming a backdoor route to infringement
  inside the EU/EEA.
- We strongly opposes proposals to introduce a SPC manufacturing exemption for export. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledge-based economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?
- We strongly oppose proposals to introduce SPC manufacturing exemption
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- The wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different). We agree with to oppose the introducing a SPC waiver. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. It must be questioned whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledgebased economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing

- perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?
- I have doubts over the evidence on which the proposal has been based. The economic benefits are not certain and the political risk of weakening EU IP protection ie.g. in future trade talks could be sigfnificant. Therefore whilst it is worth exploring because the generics industry says it would asisst, care should be taken to base future legislative decisions on reliable research data.
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), strongly opposes proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledgebased economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?
- Probably helpful for active ingredient manufacturers based in EU
- This would be a good idea in some countries because it would keep jobs within EU. However, in order to function as intended it would require an extremely well-functioning tracking system of each batch in order to make sure that all batches are exported to patent-free jurisdictions
- First, this question is clearly biased and at the same time intransparent. Where the question states that such waiver "is currently being considered", the question is, by whom, and how does that inform the SPC Survey? It appears that the generic industry is proposing such waiver. Furthermore, why are earlier questions despite complexity framed as binary yes/no questions (or no opinion), but this is an open question that does not, empirically, allow to capture objection? In substance, the concept of such waiver is at odds with the system of patent exclusivities otherwise. Introduction of such waiver would undermine the cohesiveness of the European patent system. Besides, no such waiver is available in the US or Japan, either.
- I don't believe the introduction of an "SPC waiver" to be a good idea, as a control
  mechanism to impede any exported products to be re-imported to Europe, does not currently
  exist
- I would expect no influence, because maufacturing in Europe is expensive.
- SPC waiver does not preclude and market monopoly, it just influences the selection of production site Europe vs countries such as China and India
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), we would strongly oppose proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the

existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure Further and contrary to generic industry claims, this proposal to introduce a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about EU's respect for and seriousness about building a knowledge-based economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?

- We do not agree with this idea
- Sensible idea
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), vfa (German Association of Research-based Pharmaceutical Companies) strongly opposes proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure
- Not in favour as it strengthen the notion that there should be a difference between the protection offered by a patent pursuant to non-Community principles of patent law compared to the protection offered by an SPC pursuant to the SPC regulation.
- We are strongly opposed to the introduction of an SPC waiver. It will effect innovators market
  position in important non-SPC countries, such as China, and thereby replace the export of
  high value innovator products with lower value generics/biosimilars. This will be a net loss to
  European economy and contrary to EU's ambitions for creating a knowledge-based
  economy.
- It remains a breach of the patent owners' rights and erodes IP protection. Any such manufacture would at the very least need to be with the approval of the patentee and/or subject to payment of an appropriate royalty.
- An SPC manufacturing waiver is extremly needed, The SPC Regulation as widely reconised, has the unintended consequence of forcing generics and biosimilars medicines producton to non-EU countires where no similar protection is in place. This puts the EU industry at disadvantage vis-a-vis non-EU competitors. This situation prejudices competitivenes of EU companies in the in key export markets, like for instance the US market, where patents and patent extensions will, in most cases, expire earlier than in the EU due to the more rapid introduction of new medicines. This is the case with major biological products as wall as chemical molecule products. In addition, this situation gives an unintended lead time

- advantage to non-EU based operators as regards entering EU Member States generics market immediately upon the SPC protection expiry.
- This approach is far from the interest of European generic producers and economical rational as well. While we strongly agree with the waiver in respect of production, packaging and stock-piling has to be included in the waiver too!!! If we would like to give the same economical environment for the European industry that the Indian/Chinese one, than launch in Europe on the first day after expiry has to make legal for the European manufacturers as well. It could happen only with the inclusion into the exception both packaging and stock-piling. Without these involvement, packaging, as a minimum has to be transferred outside EU. It is against economical interest of European economy.
- This would be an extremely positive step, allowing the EU generic industry to compete on a level playing field with non-EU generic companies.
- Proposals to introduce a SPC manufacturing exemption for export should be opposed. It would be a negative signal about EU's respect for and seriousness about building a knowledge-based economy if SPC as a kind of IP protection will not be respected. Additionally, it would be inconsistent with EU's trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. - The potential of such a measure to bring more highly-skills jobs back to Europe, as argued by the generic industry, is highly contested because of reducing demands of originator products leads to highly-skilled job losses in the branded sector at the same time (see analysis by Sussell et al., Journal of Generic Medicines 2017). - The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. It is to be questioned whether this is the main factor and whether there are actual opportunities given the existing competition dynamics within key export markets. - Contrary to generic industry claims, introducing a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It further deprives originators of potential licence revenues, had they licence out the right to manufacture for exports.
- We consider the SPC regulation as a whole needs to be removed due to the aforementioned reasons. If the SPC were to remain, a waiver should be applied broadly, SPC, as a typical TRIPS-plus provision, undermines generic competition, and as such a SPC should be accompanied by allowances to overcome SPC-created market exclusivities for the duration of the SPC. A mechanism equivalent to a compulsory license or government use license should be introduced as part of a broader waiver, allowing relevant government bodies to override the SPC protection when there are public health reasons to produce, import or export generic medicines.
- Proposals to introduce a SPC manufacturing exemption for export should be opposed. It would be a negative signal about EU's respect for and seriousness about building a knowledge-based economy if a SPC as a kind of IP protection will not be respected. Additionally, it would be inconsistent with EU's trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. The potential of such a measure to bring more highly-skilled jobs back to Europe, as argued by the generic industry, is highly contested because of reducing demands of originator products leads to highly-skilled job losses in the branded sector at the same time (see analysis by Sussell et al., Journal of Generic Medicines 2017). The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. It is to be questioned whether this is the main factor and whether there are actual opportunities given the existing competition dynamics within key export markets. Contrary to generic industry claims, introducing a SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing - substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It further deprives originators of potential licence revenues, had they licence out the right to manufacture for exports.

- Would be good to have a possibility to strengthen competitiveness of European based manufacturing industry without effectively weakening the SPC-protection for the European market:
- While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), we are strongly opposed against proposals to introduce a SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skills jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure.
- Would bei a progess and enhance competitiveness of European manufacturers.
- This question is biased. It is also intransparent. Who considers such waiver? The framing is not acceptable, either. Other questions are yes/no or favor/oppose. This is an open question that does not, empirically, allow to express opposition. In substance, the a waiver is incompatible with the system of patent exclusivities. By comparison, no such waiver is available in the US or Japan, either.
- SPCs are created to stimulate investments in further R&D. SPCs should provide the same scope of protection as the basic patent confers. The introduction of an SPC Manufacturing Waiver would be detrimental to the development of future innovative plant protection products in Europe and globally. Furthermore it would be a negative signal about EU's respect for and seriousness about building a knowledge-based economy if SPC as a kind of IP protection will not be respected. Additionally, it would be inconsistent with EU's trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. The potential of such a measure to bring more highly-skills jobs back to Europe, as argued by the generic industry, is highly contested because of reducing demands of originator products leads to highly-skilled job losses in the branded sector at the same time (see analysis by Sussell et al., Journal of Generic Medicines 2017). The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. It is to be questioned whether this is the main factor and whether there are actual opportunities given the existing competition dynamics within key export markets. Contrary to generic industry claims, introducing a SPC Manufacturing Waiver could also have an effect on European originators' exports to these markets, which is the market on which Europe and generics which could cause job losses in the EU's innovative plant protection sector. It further deprives originators of potential licence revenues if the licence does not cover the right to manufacture for exports.

Q 68: Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force?

- Other (please specify) -
- License fee to the benefit of the SPC/patent holder according to normal business terms.
- Financial compensation such a licence fee of the SPC holder
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit

meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.

- The more measures to prevent abuse of a waiver the better. Unfortunately such abuse can never be ruled out.
- An additional measure would be to grant patent/SPC holders the right to enjoin the
  manufacturer from manufacturing/shipping the product or introducing a penalty system
  whereby a manufacturer is barred from using the waiver after a violation thereof.
- (1) Licence fee to the benefit of the SPC/patent holder (2) a certain percentage of the generic product should be exported to least developed countries in order to improve access to medicines in those areas; such exports to be royalty free.
- We cannot see that any safeguards would be sufficient.
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- license fee for right holders
- Licensee fee for SPC/patent holder according to normal business terms
- Some form of "track and trace" for batches of product manufactured under the waiver would appear to be necessary to prevent misuse of the waiver (e.g. by stockpiling product abroad and then reimporting it immediately after SPC expiry).
- Licence fee to benefit of the SPC patent holder according to normal business terms.
- License fee to the benefit of the SPC/patent holder according to normal business terms.
- Loss of right to manufacture under the waiver, if waiver violated. Presumption of violation of waiver upon filing of patent issued by country to which product has been exported under waiver. Royalty/license fee payable to patent/SPC holder. Right to injunction to stop export during resolution of dispute, if reasonably likely waiver is being violated. Right to seize and destroy product manufactured in violation of waiver.
- License fee.
- license fee to the benefit of the SPC/patent holder according to normal Business Terms All possible measures providing some possibility to Permit meaningful enforcement of the Terms of such a waiver without permitting infringing use.
- introduce mandatory license fee to right owner under normal business terms
- To prevent stockpiling abroad the product itself would have to be identifiable as a "manufacturing waiver" product and there would have to be no right to reimport the "manufacturing waiver" product after the patent or SPC expired.
- Perhaps intrdocuing a lag period corresponding to the time the generic manufacturer has been able to optimize the production. A period that would otherwise start later.
- Financial compensatory mechanism for the patent/SPC holder
- A licence fee and safeguards to ensure rapid action to counter breaches of conditions for the waiver.
- Compensation for the erosion of rights should be considered, not necessarily in the form of a license but looking at the incentives package as a whole.
- License fee to the SPC holder

- Manufacturing and stockpilling have to happen together and job creation has to be demonstrated
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- We support Efpias comments
- There is no need for such measures. Pharma market is so much regulated that any missuse of
  the manufacturing will be detected immediately if marketed within the EU. In third countries
  where the patent is still in force, there are effective measures to know the origin of the
  product and to stop it.
- all these and possibly more measures would be necessary to create fair and effective protection.
- Reasonable license fee -Full description of the manufacturing process and quality profile of the API -Safeguards to ensure the manufacturing is only for export in countries where there is no Patent. Indeed, generic companies are companies like any other. And the first objective of a the generic company is to generate value i.e. target countries where companies can have the best business case (margins). So generic companies might try to misuses this system to enter markets and prepare market entry into high value countries where the product might still be patent protected. Generic companies do unfortunately not export their products broadly in all worldwide countries because it would not generate enough cash (although the originator products are most of the time approved and marketed in such lower value countries) and very often focus on the most profitable markets only. Pharma industry has a much higher public, ethical and political pressure to bring its drugs (in particular lifesaving drugs) into all the global markets for the benefits of patients.
- Fees for the benefit of the SPC holder under standard business rates.
- Realistic licence fee to SPC holder. Measures to prevent stockpiling and springboarding.
- The patent holder should however be required to give a response within a reasonable deadline, say 30 days, indicating his intention to accept or seek court proceedings. Notification alone may leave things in suspense, which is not an incentive sought by the measure.
- License fees to the benefit of the SPC holder and ensuring that the safeguards listed in this question are enforceable without undue burden.
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- License fee to the benefit of the SPC/patent holder according to normal business terms.
- License fee to the benefit of the SPC/patent holder according to normal business terms.

- A central register of activity under trhw waiver could be created for patentees/SPC holders to check. Pro active detialed information disclosure should not be required.
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- License fee to the benefit of the SPC/patent holder according to normal business terms. If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- Payment of a compulsory royalty for use of the patent.
- Specification of "Other": Licence fee to benefit of the SPC patent holder according to normal business terms.

Q 68: Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force?

- additional comments -
- The healthcare sector is a patent-intensive sector and it is expected that SPC protection will remain a critical incentive for healthcare innovation. opposes the introduction of an export manufacturing exemption because: (i) it would not generate any material overall economic benefits in the European Union, (ii) it is likely to undermine the integrity of an important intellectual property right for the healthcare sector, and (iii) it could be detrimental to the development of future innovative (bio)pharmaceuticals in Europe and globally.
- If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- All or a variation of these measures could be helpful. They are not mutually exclusive.
- This is an explosion of buerocracy

- If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected
- The healthcare biotechnology sector is a patent-intensive sector and it is expected that SPC protection will remain a critical incentive for healthcare innovation. poposes the introduction of an export manufacturing exemption because: (i) it would not generate any overall economic benefits in the European Union, (ii) it is both likely to undermine the integrity of an important intellectual property right for the healthcare biotechnology sector, and (iii) it would be detrimental to the development of future innovative biopharmaceuticals in Europe and globally.
- Any such measures would again favour the production outside of Europe where no such measures exist
- For a manufacturing waiver for stockpiling the same arguments apply as for the export waiver: Independently from where the generic product is produced - it will be on the market at Day 1 after patent expiry (which is intended as the economical monopoly of the originator ends at exactly this day) - it won't be on the market before - as it cannot be listed in any necessary reimbursement scheme It is not a competition between originator and generic but between Non-EU- generic and EU-generic.
- The issue of infringement is always dealt with nationally. IF it transpires that the product was manufactured illegally then that is a separate issue, ie it is entirely possible that I can source a product from India where an Indian patent is infringed. It is dealt with in India not in the UK. Similarly if there is a breach in the EU it is dealt with in the country of manufacture.
- Why should that become necessary? Why should stockpiling not be allowed? Where is the difference from importing the drugs from Russia (outside EU) to Germany (inside EU) as compared to importing the drugs within the EU such as from Denmark to Germany? I suppose it is assumed that the manufacturers would like(!) to infringe existing SPCs and patents and this wouldn't be picked up due to the lack of border control availability. But honestly, this threat is not substantiated. How often have pharmaceutical products indeed entered the market before SPC expiry? There is no risk with a manufacturing waiver that generics and biosimilars enter the market before SPCs expire. The rules in place today to avoid that this happens will not change at all with an SPC MW. EU countries have all the necessary legal tools to block and seize infringing pharmaceuticals before they reach the market (e.g. preliminary injunctions), and this will not change. NB. until very recently, in eastern European countries, where SPCs where not in place yet, there were already generic products on the market that were unprotected in those markets but still protected in Western EU markets. This did not create infringement issues in protected markets, which shows that an SPC manufacturing waiver would not create any specific risks, either. The SPC MW is only about entering the market and creating competition immediately after SPCs expire. Currently European companies today cannot do it. Either they produce abroad, or they enter the EU market over 6 months after SPCs expire, while others are already there. The SPC manufacturing waiver is not about competitiveness between SPC holders vs. generics. It is about competitiveness between European pharmaceutical industries.
- If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected. Assuming a waiver were introduced, such a waiver should not be deemed to be effective against other IP rights including other patents that may cover the product for export.
- The proposed manufacturing waiver would be very difficult to enforce placing a significant burden on both the judicial system and innovators. Even the generic companies would be

burdened, as they would have to implement procedures to document compliance with the waiver and to prevent violation of the waiver, which would add to their costs of goods, which costs of goods are already higher than those of their generic competitors manufacturing in developing countries. Further, enforcement of the waiver may require interpretation of foreign law (does the EU patent holder's patent in the export country cover the product?) and gathering of evidence from foreign jurisdictions (e.g., proof that product is located in an export country in violation of the waiver). All of this cost and burden is in stark contrast the fact that little or no economic (or competitive) harm is coming to the generics by virtue of being prohibited from infringing an innovator's patent by manufacturing product during the term of an SPC.

- It would be useful to add a marker to product and if it the product is found in the EU, then the generic manufacturer should be fined
- The introduction of such a waiver would result in a Need to implement a variety of safety measures aiming to prevent abuse which would create additional legal complexity and factual uncertainty without being likely to prevent abuse. Moreover it is entirely unclear what the economic consequences would be for the pharmaceutical industry altogether. The softening up of IP rights might moreover send bad signals to non-EU countries about EU's respect for and seriousness about building a knowledge-based economy and about how seriously IP rights are taken in the EU. Altogether, such a waiver should not be introduced.
- The manufacturing waiver introduced by legal measures makes no sense and therefore it should be negotiated by the parties on arms-length-basis subject to compensation payments!
- I believe stockpiling and manufacturing should be allowed
- If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- All this would be curing symptoms of a malaise that should not arise in the first place.
- Limitation in stockpiling drives the production from Europe to other countries such as China and India
- There is no need to prevent exportation to countries where equivalent protection is still in force; it would be a matter for the courts in that country to determine whether the product infringes said protection. The prevention of stockpiling would undermine what we understand is the primary purpose of the manufacturing waiver to put European generic companies on a level playing field with non-European generics companies. A European-based generic must be able to manufacture sufficient product to meet launch requirements upon SPC expiry and therefore stockpiling should be allowed, at least in the final 6 months of the SPC term.
- Specification of "Other": License fee to benefit of the SPC patent holder according to normal business terms.
- when requiring the manufacturer to disclose information to the SPC-holder, that could consist
  of trade secrets, measures of protection for those secret business information should also be
  provided, e.g. by asking a neutral, independent third person to check and confirm quantities
  and exports into patent-free countries
- Significant License fee to the benefit of the SPC/patent holder to compensate for lost profits.
   If such proposal were pursued, it would be important to include all such safeguards as proposed in this question to provide measures that at least have some possibility to permit meaningful enforcement of the terms of the "waiver" (i.e., manufacturing solely for export to those jurisdictions without IP protection) without permitting infringing uses. However, the

- undue complexity that would have to be introduced underscores our view that the "manufacturing waiver" proposal itself should be rejected.
- All this would be curing symptoms of a malaise that should not arise in the first place.

## Q 70: And in your opinion, which authority shown on this list should grant a "unitary SPC"?

- additional comments -

- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- The unitary SPC shall be examined and granted by experienced examiners from national patent offices, since the importance of the unitary SPC is even greater than the relevance of the current bundle of SPCs.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- Given the number of possible cases each year (below 100) the "virtual office" joining the best examiners with a very thin administrative burden would be fantastic as a model for a "21st century Office"
- We have read and agree with the comments that we understand will be submitted by EFPIA
  in response to this question. Such a virtual office could in some way be connected with, or
  hosted by, the EPO or EUIPO.
- The examination and granting of a "unitary SPC" should be transferred to the EPO but with the obligation to use the knowledge and experience of the national experts; this could be done by forming examination divisions where national and european examiner working together.
- SPCs with unitary effect should be granted by a virtual body composed of SPC experts from
  national patent offices. That is virtual does not mean it does not exist this virtual office would
  need to be legally created and embodied, eventually under the roof of an EU body such as
  the EU IPO, and supported by a performing IT system. The appeal process should be before a
  court. Further, it should be clarified whether this could be the UPC because of technical
  competences.
- supports the creation of a Unitary SPC and the suggestions by several industry associations for the establishment of a "virtual body composed of SPC experts from national patent offices" as the delegated authority to grant unitary SPCs. Decisions of the virtual body would be challengeable in a court system. Similar to a Unitary Patent, a Unitary SPC would reduce internal time and resources needed for SPC filings in each Member State, and would help ensure harmonization of SPC guidelines and best practices.
- In our view, the virtual office needs an institutional framework. For this purpose, one may
  consider involving the EUIPO as a true European Office.

- To be set up along the following criteria: Sufficient expertise is needed. Centralized granting procedure to achieve necessary harmonization. A virtual office could be set under the roof of an EU body, the EUIPO. It should be clarified whether in addition to normal court route to the CJEU, the UPC can be chosen as additional route for material law questions.
- The virtual office could be established using patent examiners out of national patent officers, eventually under the roof of an EU body such as the EU IPO. The appeal process should be before an EU court. Further, it should be clarified whether an alternative option could be the UPC because of technical competences.
- The EPO can be a good choice provided that the specialised EPO's Examiners are devoted only to the SPC examination and not the EP patent prosecution.
- The EMA (because the EMA knows best whether a full study program had been necessary for approval) and the EPO (or a national patent Office) to see whether the product is covered by the claims. It should be a common task.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- A virtual patent office would seem to be the most efficient way to create a unitary SPC and
  would permit use of SPC experts existing already in national patent offices. The "virtual" office
  would still need legal structure around it, as well as some administrative support; for example,
  the office might be hosted by a competent EU agency or body or it might be a stand-alone
  institution. The key is to leverage existing procedures, rules and expertise to create an
  efficient, reliable and predictable unitary SPC process/right.
- EMA would NOT be a could alternative, since the SPC system is basically a particular part of the patent system. Giving the granting procedure to EMA bears the risk that too much emphasize is given to the regulatory part of the SPC system. This is, however, only a "trigger" for the patent based SPC system.
- see existing joint proposal from EFPIA-ECPA- IFAH
- Experts from EMA should also participate in the process
- The Agency department to which the activity is demanded should include patent experts
- It should be litigated always at the Unified Patent Court.
- This can be created based on the already existing expertise in the national patent offices. We can select national experts collaborating with each other in a pan-European structure (like the regulatory authorities collaborating together). Three examiners from different offices (randomly selected) can be designated to perform the examination and prepare a proposal. The final decisions are then taken during a monthly centralized meeting between the examiners. A few administrative staff can be located at a centralized location to coordinate the activities, IT, decision making process, decision publications, etc.
- We think a virtual office is a great idea since it will utilise the existing expertise of current national experts. Whoever came up with this idea is a genius. It would reduce regulatory burden on SPC holders significantly. A unitary SPC would lead to greater legal certainty, particularly if compared with litigating national SPCs in the Unified Patent Court. A unitary SPC is a natural consequence of the introduction of Unitary Patents. We think the language regime of any such office is relatively unimportant. A virtual office would avoid the forum shopping that would occur under a mutual recognition procedure.

- A virtual patent office staffed with SPC experts from national patent offices and administered by a central EU body or the EPO
- For a virtual patent office to work successfully, it is very important that examiners are properly trained and guidelines are provided to ensure consistency of approach.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognized that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. We support that approach.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- If new medical uses of known active ingredients are only SPC-eligile under certain circumstances such as equivalent clinical trials, it makes sense to involve the EMA. However, (national) patent examiners should always be involved in the decision.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- Any proposal for a unitary SPC to be granted by National patent offices based on mutual recognition system could result in serious uncertainty. Different offices may apply the various tests/standards differently, which is likely to result in forum shopping and divergent decisions.
- The virtual office could be established using patent examiners out of national patent officers. The appeal process should be before the UPC.
- The virtual office could be established using patent examiners from national patent offices.
   The appeal process should be before the Unified Patent Court (UPC).
- the EPO could provide the institutional framework and could perform the examination and
  grant of unitary SPCs as a special tasks on behalf of the participating member states of the
  Unitary SPC (analogously to the EPO is handling all aspects of the unitary effects of European
  Patents); this could be combined with the idea of a virtual office, by allowing national offices

- of participating member countries to send/assign examiners to the EPO body dealing with Unitary SPCs; such a model exists already for the Enlarged Board of Appeal at the EPO where external members are provided by EPC member countries.
- ECPA, EFPIA and IFAH-Europe have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light.
- SPCs with unitary effect should be granted by a virtual body composed of SPC experts from
  national patent offices. That it is virtual does not mean it does not exist this virtual office
  would need to be legally created and embodied, eventually under the roof of an EU body
  such as the EU IPO, and supported by a performing IT system. The appeal process should be
  before a court. Further, it should be clarified whether this could be the UPC because of
  technical competences.

## Q 76: Do you have any further comments, questions or criticism regarding the current SPC regulations or case law or on other aspects regarding SPCs that have not been addressed in this survey and that are important to you?

- supports the creation of a Unitary SPC and the suggestions by several industry associations for the establishment of a "virtual body composed of SPC experts from national patent offices" as the delegated authority to grant unitary SPCs. Decisions of the virtual body would be challengeable in a court system. Similar to a Unitary Patent, a Unitary SPC would reduce internal time and resources needed for SPC filings in each Member State, and would help ensure harmonization of SPC guidelines and best practices.
- The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. Our member companies are the main users of this system, filing and prosecuting SPC applications every day. As such, we would like to provide our impression of the system's operation in general. • The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring new medicines to patients. • As a result, the critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, we believe this is not necessary and on the contrary, that a proposal to re-open the SPC Regulation would be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. • First, we believe that the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which about 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or denied without

any issue. Given the high value of SPCs for innovative biopharmaceutical companies and the fact that SPCs operate in an inherently very litigious phase of a pharmaceutical's life, this number of referrals is not unreasonable. These numbers indicate that, in a vast majority of cases, the Regulation has worked well to compensate the industry for the delays necessary to bring innovative biopharmaceutical products to the market. Within this background, the SPC Regulation has met and is meeting its policy objectives. • Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. We believe that, although there will be new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come. • Due to the nature of innovation, further circumstances that may require clarification could arise. However we believe that this does not justify amending the Regulation. It is indeed unlikely that these points, or others, could be clarified satisfactorily or comprehensively with a new Regulation and any new provision or wording would inevitably raise new questions for interpretation by the CJEU, especially factoring in the likelihood of disputes inherent to our sector over these valuable rights. We would therefore favour retaining the existing Regulation and leave it to the CJEU to clarify pending questions as they arise.

- "Date of authorisation" vs. "Date of notification of authorisation" should be clarified and harmonized within EU countries.
- To sum up, the grant of SPCs based on the present SPC Regulations under consideration of the CJEU's case law is working very well. Therefore, the existing SPC Regulations should not be amended. However, an additional SPC Regulation should be created covering new technologies, which are not encompassed by the existing Regulations.
- For generic and biosimilar medicines producers it is of utmost importance to ensure the highest level of transparency in SPC granting procedures. Today some European countries are more transparent than others. Third party observations and oppositions should also be taken more substantially into account. As a general comment, while there is an urgent need for an amendment to art. 5 of the SPC regulation in order to rapidly introduce an SPC manufacturing waiver, all the other aspects of the SPC regulation would need a deep reflection on the best way to clarify the terms os the regulation in light of the jurisprudence.
- The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. The opportunity for different discussions are the main users of this system, filing and prosecuting SPC applications every day. As such, we would like to provide our impression of the system's operation in general. • The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring new medicines to patients. • As a result, the critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, believes this is not necessary and on the contrary, that a proposa open the SPC Regulation would be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. First, believes that the number of referrals to the Competitive and the SPC Regulation Are believes this is not necessary and on the contrary, that a proposal to repharmaceutical innovation. • First, believes that the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which about 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or

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- SPC regulations have a poor language which was due to political compromises Such political compromises may be smart for politicians but they are hell for the practitioners that have to work with such law. We suffer on a day-to-day base for decades because uninformed laymen (politicians) thought they made a proper job. However, it is not so: the 1992 Regulation was bad law and continued to be worsened by the CJEU decisions on this language As the CJEU decisions show, the compromise language of the SPC regulations have also been a nightmare also for the CJEU and not only for the practitioners (bad law makes bad decisions)
- SPC regulation is not presently clear regarding: In the field of Crop Protection, conduction of field trials, by a third party, before patent expiry, in order to obtain marketing authorization for commercialization after patent (SPC) term. This situation is perfectly clear in the field of pharmaceuticals but lacks the clarity for Crop Protection products.
- believes that unitary SPC for the agrochemical sector: Important to provide harmonization and to unify the significant variations that currently exist between national systems. Consequently, innovation in agriculture will be fostered. - Unitary SPC for agrochemicals could be granted. - Should be based on the EU-wide approval of the active ingredient by the first product approval within the EU and should only have effect in the territory of those member States, where a product approval exists at the expiry of the basic patent.
- costs and timelines for court cases involving SPCs should be unified
- Overall considers that the SPC Regulation has worked well and delivered against its initial objectives, i.e. compensating for the effective protection period lost due to the lengthy development process and regulatory approval timelines. When compared to the overall number of SPC applications, the number of referrals to the CJEU is relatively small. It is inevitable that from time to time some cases will require the interpretation of the CJEU, but these remain exceptions and do not warrant a revision of the SPC regime in force in the EU.
- Given the variability and uncertainty of the decisions in the SPC area we stringly support unified SPC regime. And as a generics association, we definitely strongly support also the manufacturing waiver.
- At all times, we believe we should keep the rationale of the SPC system in mind: to make up for the time lost in meeting regulatory requirements and obtaining a license prior to commercialisation. That is the only justification for treating pharmaceuticals and plant protection products different than other technical products. It should be realised that SPC applicants can strategically manipulate the date of their MA by filing relatively late or by delaying the regulatory process, so that the MA is granted at a moment that allows them to obtain SPC for the full term of 5 years. Also, it should be critically examined whether the first MA is indeed a MA obtained on the basis of a truly full dossier for a truly new active ingredient or type II variation and not for, in fact, a line extention or minor variation

- I have handled many hundreds of SPC applications on behalf of my company, and in the vast majority of cases these progress smoothly and without any issues. In the very few cases where there are issues, I was always aware in advance that those cases were at the margins, and would likely face difficulties. Recent caselaw from the CJEU has in my view provided even more clarification, and I am more convinced than ever that there is no need for a change to the Regulation. Any change risks causing increased uncertainty, and as a very active user of the SPC system, I believe that any changes are wholly unjustified.
- The following (or very similar) comments have also been made in the response submitted by EFPIA, of which we are a member organisation. These comments fully reflect our views. The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. As experienced users of this system, filing and prosecuting numerous SPC applications, we would like to provide our impression of the system's operation in general. The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring a new product to the market. • The critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, we believe this is not necessary and on the contrary, that a proposal to re-open the SPC Regulation would be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. • Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. We believes that, although there will be new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come.
- Referring to Q 46: Divergent to the pharma-sector the crop-protection sector is of the opinion that the mentioned decisions don't provide a clear criterion, so the answer to question Q 46 is "UNCLEAR CRETERION". I addition the answer to Q 47 in view of the cropprotection-industry is "STRONGLY DISAGGREE". • Referring to Q 75: The crop-protection and pharmaceutical industry advocates for a quick introduction of a unitary-SPC for pharmaceuticals and crop protection products. Only through the introduction of such a unitary SPC for these areas it can be ensured that the advantages offered by the new European patent system could be used by the companies. Due to the high investments in the research and development of their innovative products, companies rely on effective protection through SPC. The missing possibility to obtain a unitary SPC leads to a significant gap in the protection intellectual property in Europe. Without the opportunity to obtain a unitary SPC there is a high risk that companies in the pharmaceutical and plant protection sector will not or only reluctantly use the new system and the associated advantages will remain unused. It is, therefore necessary to create a unitary SPC by means of a separate regulation until the first European patent with unitary effect is granted. As for current SPCs, unitary SPC should be available based on a European patent with unitary effect and a marketing authorisation, irrespective of whether it is centralised and granted by the EMA or national and granted through the decentralised or mutual recognition procedures. If unitary SPCs were to be available only to products granted through the centralised procedure, it would unduly discriminate against certain products which are not eligible for the centralised procedure. In the absence of a centralized granting procedure (agrochemicals), the unitary

SPC should be granted based on the EU-wide approval of the active ingredient by the first approval in a Member State. It should have unitary effect in those member states who have granted authorizations regarding their own territory for the same product as the first authorization granted by a first Member State at the expiry date of the basis patent.

- In our experience the current SPC Regulation works well in most cases and does not need amending. An amended SPC Regulation would not lead to clarity but instead would lead to further litigation and referrals to the CJEU. There are valuable rights which will always be the subject of dispute with parties testing the boundaries of the law or testing the law in novel situations. We are in favour of the system which as it currently stands compensates these developing medicinal products where they have suffered delay in obtaining statutory marketing approval.
- First, the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which about 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or denied without any issue. Given the high value of SPCs for innovative biopharmaceutical companies and the fact that SPCs operate in an inherently very litigious phase of a pharmaceutical's life, this number of referrals is not unreasonable. These numbers indicate that, in a vast majority of cases, the Regulation has worked well to compensate the industry for the delays necessary to bring innovative biopharmaceutical products to the market. Within this background, the SPC Regulation has met and is meeting its policy objectives. • Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Although there will be new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come. • Due to the nature of innovation, further circumstances that may require clarification could arise. However this does not justify amending the Regulation. It is indeed unlikely that these points, or others, could be clarified satisfactorily or comprehensively with a new Regulation and any new provision or wording would inevitably raise new questions for interpretation by the CJEU, especially factoring in the likelihood of disputes inherent to our sector over these valuable rights. We would therefore favour retaining the existing Regulation and leave it to the CJEU to clarify pending questions as they arise.
- would like to express serious concerns regarding the way in which this important survey is being conducted and the considerations given to users' views, i.e. views of those companies which file and prosecute SPC applications and rely on the protection that SPCs provide to invest substantially and sustainably into research and development. The formulation of the questions is not of a quality which allows for collection of the whole spectrum of views of stakeholders. The extension of the dealdine for filling the questionnaire was granted only after several associations registered their dissatisfaction with the process for collecting feedback with the European Commission.
- no
- Most of the uncertainties focus around Art 3 and have already been addressed in your
  previous questions. Other issues are the entitlement of an SPC in accordance with Art. 3 (2) of
  the SPC Regulation 1610/97- eg. if there is overlapping ownership
- Whilst the legislation does perhaps have some imperfections, my main concern relates to the way in which certain judgements of the CJEU have interpreted the legislation. Whilst not all of the CJEU's judgements on SPCs are problematic, a significant proportion of them reveal: a (serious) misunderstanding in connection with important (legal and/or technical) details; logical flaws; and/or a failure to consider a broader perspective (e.g. how a particular interpretation might have troubling consequences in cases having different underlying facts). Thus, in my view, the most significant improvement to the functioning of the SPC system would be to ensure that the CJEU is adequately supplied with individuals (including judges) who have a level of understanding to match that of "specialist" IP courts in countries such as Germany and the UK.

- The current system works well in the vast majority of cases, and the Regulation does not need amendment. The courts are playing their role in clarifying any uncertainties.
- no
- 1. In case, the CJEU case law should be taken into account, the following change for article 3.1 (b) should be considered (e.g. "Georgetown"): New 3.1 (b4). The grant of a certificate is not precluded merely because the plant protection product in b) comprises one or more other products which are not the subject of the application for a certificate. SPCs are intended to compensate the owner of a patent for loss of effective patent term due to regulatory delays which have the effect of delaying the launch onto the market of a product protected by the patent. It naturally follows that any patented product that requires regulatory approval, and for which approval, and thus putting on the market, is delayed should in principle be eligible for an SPC. It makes no sense to differentiate between chemical compounds, mixtures, formulations devices or whatever. If a patent has been granted and there is regulatory delay, then an SPC should, in principle, be available. New regulation EC No 1107/2009 should be taken into account (so far there is only reference to 91/414/EEC! believes that unitary SPC for the agrochemical sector: Important to provide harmonization and to unify the significant variations that currently exist between national systems. Consequently, innovation in agriculture will be fostered. Unitary SPC for agrochemicals could be granted. based on the EU-wide approval of the active ingredient by the first product approval within the EU and should only have effect in the territory of those member States, where a product approval exists at the expiry of the basic patent.
- No abandonment by the SPC owner ex tunc possible. Unitary SPC for agrochemicals could be granted based on the EU wide approval of the active ingredient by the first product approval within the EU and should only have effect in the territory of those member states, where a product approval exists at the expiry of the basic patent. The case law regarding SPC should be taken into account in its entire and not only in regards to specific decisions. This could be done best via guidelines. SPCs will fall under the jurisdiction of the UPC, which could further develop and harmonize case law in this regard.
- Make it clear and easy to understand that helps all parties involved. "Rechtssicherheit" is the one interest we all share. One SPC per product. Clear Expiry Dates. The late decision of the EUGH that the SPC expiry date now Needs to be calculated from the date of the "notice of the approval" rather than the approval was unnecessary complicating the situation and results in different expiry dates per country. That helped noone. Should be fixed back with a clear legislative correction.
- Current SPC regulations have worked well in practice and reasonably balanced the interests of all relevant stakeholders. Any major change to the current regulations would upset the investment-backed expectation, and create confusion, ambiguity and therefore unwanted litigation. Specifically, the proposed SPC manufacturing waiver relies on naive and incorrect assumptions. Such waiver would also be difficult to implement in view of the fact that a complex product such as a pharmaceutical drug is often protected by multiple patents, and an exemption of SPC on one patent does not relieve the manufacturer's liability for infringing other patents. At the end, R&D investment and innovation only starts with the invention of the active molecule. Significant further development is required before that active molecule moves from the laboratory bench to a commercial product, all of which requires significant R&D invenstment which should be protected by the SPC Regulation. In addition, we agree with the concerns expressed by EFPIA, which are reproduced below: The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. EFPIA member companies are the main users of this system, filing and prosecuting SPC applications every day. As such, we would like to provide our impression of the system's operation in general. • The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmacéutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring new medicines to patients. • As a result, the critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing

authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, believes this is not necessary and on the contrary, that a proposa open the SPC Regulation would be detrimental to the EU competitiveness as a hub for believes this is not necessary and on the contrary, that a proposal to repharmaceutical innovation. • First, believes that the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which about 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or denied without any issue. Given the high value of SPCs for innovative biopharmaceutical companies and the fact that SPCs operate in an inherently very litigious phase of a pharmaceutical's life, this number of referrals is not unreasonable. These numbers indicate that, in a vast majority of cases, the Regulation has worked well to compensate the industry for the delays necessary to bring innovative biopharmaceutical products to the market. Within this background, the SPC Regulation has met and is meeting its policy objectives. • Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. number of these points which were raised to it. believes that, although there will be new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come. the nature of innovation, further circumstances that may require clarification could arise. believes that this does not justify amending the Regulation. It is indeed unlikely that these points, or others, could be clarified satisfactorily or comprehensively with a new Regulation and any new provision or wording would inevitably raise new questions for interpretation by the CJEU, especially factoring in the likelihood of disputes inherent to our sector over these valuable rights. would therefore favour retaining the existing sector over these valuable rights. Would therefore favour retaining the Regulation and leave it to the CJEU to clarify pending questions as they arise.

While we understand that there is a certain level of pressure to re-open the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to the CJEU under the Regulation reflects a lack of clarity, we believe this is not necessary and on the contrary, that a proposal to re-open the SPC Regulation would be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. Re-opening the SPC regulation would result in tremendous uncertainty about the final outcome of the process, and at a time when there is already uncertainty with respect to future rights/business practices in the industry, due to the impending exit of the UK from the EU. There is no need to re-open the Regulation - it is working as intended and only a limited percentage of SPCs are disputed with even fewer resulting in referral - and in the meantime other more pressing issues are actually creating business uncertainty and will demand more attention; for example, implementation of the UPC/UP system and negotiation of terms for "Brexit." (We note that of about 21,000 national SPC applications, only 30 cases have been referred to the CJEU and the majority of those (about 90%) have been granted or denied without any issue.) A primary purpose of the SPC Regulation is to compensate those who invest the time and money into (and take on the significant business risk of) bringing innovative medicines to patients because "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research. (Recital 4 of the SPC Regulation - 469/2009/EC) However, the full term of the patent is not restored. No more than 5 years of lost term are granted and only to a maximum of 15 years of patent+SPC term after marketing authorization. Thus, an SPC can never restore a patent's term to the full 20 years, and an SPC extended patent can never provide more than 15 years of "exclusivity" the MA holder. (The possible 6 month paediatric extension, not withstanding.) This Regulation is aligned with similar regulations elsewhere around the world. It provides welldefined, predictable protection for the product and properly values the innovator's investment and the value of patents in stimulating innovation and competition. There is no need to create uncertainty by re-opening the legislation, particularly when so much of the

- "criticism" of the system is based on ignorance of the economic facts and business practices of the industry and erroneous assumptions about the scope and effect of the Regulation.
- In an overwhelming majority of cases the SPC Regulation works well and meets its objectives without any ambiguity or recourse to litigation. As with any legislation, some issues have required clarification and given the commercial value of SPCs this has led to some high profile litigation. However, this arises in a small fraction of cases and the existing case law has already resolved many issues and will bring further clarity as the case law develops. If the practice of national patent offices need to be harmonised with the case law, this can be done through commission guidelines. Changing the Regulation as seemingly proposed in this survey will merely introduce further legal uncertainty.
- IT is imperative for the plant protection industry that they specific market dynamics and their specific procedures are taken into account. The infringement test is much easier to recreate legal certainty.
- No
- The present Survey does not provide for the opportunity for an Overall assessment of the Operation of the SPC Regime in Europe. New efficient and safe medicines are critical for public health. The necessity of conducting extensive pre-clinical and clinical studies bevore a new medicine can be marketed, but necessarily after the filling of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate sufficient Revenue to sustaint the significant stream of Investments required to bring new medicines to the market for the benefit of the patients. As a result, an effective SPC Regime is of critical importance to the innovative pharmaceutical industry and to public health which needs the development of new efficient and safe medicines. The Regulation has been largely clarified by means of caselaw which will also be able to deal with the future evolvement of medicine and science. The SPC Regulation should thus be retained and it should be left to the CJEU to clarify pending questions as they arise. In this respect, the comments to be provided by the EFPIA by written letter to the MPI are highly relevant.
- SPCs are critical to the continued investment of the research-based pharmaceutical industry
  to develop innovative medicaments to address patients needs. Due to long development
  timelines and the regulatory review period the "effective patent term" i.e. the time period
  during which the marketed product is protected is too short to recoup in investments. The
  current regulation acknowledges these needs (5 years max, 15 year cap). The system is
  functioning as evidenced by the small number of cases referred to the CJEU for further
  clarification of certain points of law.
- We would like to comment further on a number of questions for which no comment box was provided, but which in our view require more than a simple tick-box answer. Numbering refers to the recently-circulated pdf (MPI-SPC/3754/Final). Q26a) First statement It seems to us that 'prevent' is a very high hurdle given that there are various factors involved in deciding where to base research centres. We suggest that 'discourage' or 'deter' would have been more appropriate in this question, in which case we would have agreed with the statement. Q26b) First statement it was not clear what was meant by 'longer time' - longer than what? Third statement SPC's can currently be obtained in relation to medicinal combination products in a number of different circumstances. This has been clarified by various decisions of the CJEU, eg C322/10 (Medeva) and C422/10 (Georgetown). We believe it is preferable for further clarification to evolve organically through decisions of the CJEU as new situations arise. Fourth statement SPCs can currently be obtained in some circumstances for new medical uses. However the main issues regarding effective protection for new medical uses are (a) obtaining such patents in the first place, given the increasing requirements of clinical data transparency and (b) enforcement of such patents in view of 'skinny labelling' and the potential for off-label or cross-label prescribing. Whilst we have no criticism of clinical data transparency per se, it can make it difficult to file an appropriate patent application before the relevant information is in the public domain. Similarly we fully agree that once patents relating to the first indication for a medicine have expired, generic products for this use should be available. However, we believe there should be an effective mechanism to protect IP rights on later innovations relating to additional uses. Q34 - Although development of NCEs generally requires more effort and investment than development of new formulations or indications, this is not always the case. In our view the potential length of legal protection should be the same in all cases. In any event, where development times are short, it is already the case under the current SPC Regulation that the term of supplementary protection will be shorter, or no SPC is available. Q35– The question of incentivizing development of new

antibiotics is a complex issue and would not be solved by amending the SPC Regulation Q37 - Incentives for orphan drugs are provided by the Orphan Medicinal Product Regulation Q44 - As noted in our response to Q43, we believe that any new definition, including the one proposed in this question, would simply be subject to further interpretation and ultimately references to the CJEU. Q65 - This question requires a more nuanced and detailed answer than the options available. We would support an interpretation of the Bolar exemption which provides parity for innovator and generic companies in terms of the permitted activities, as is the case in many EU countries. Q69 - This question also requires a more nuanced and detailed answer than the options available. Whilst a 'unitary SPC' may be a desirable option in light of the unitary patent, it would be important to ensure that there is an effective and efficient working system for granting said rights.

- Although it has been addressed, I would like to stress the importance of clarity and predictability as well as harmonisation within Europe. The current status is very unsatisfactory.
- Yes, I have not seen any plant protection specific questions. Of particular interests are
  questions of a Unitary SPC for plant protection products which have been approved not in a
  centralized procedure.
- I think the whole problem behind the Article 3a questions have arisen from the fact that there is a certain type of combination products that the CJEU seem not tolike. To this extent this has created too much inclarity. This could perhaps be solved e.g. by amending Art 13 and add teminal disclaimer like provisions so that only a second SPC could be granted with longer duration based on same MA and basic patent if the product was patentable distinct. New patent same MA different situation. Just a though on a more managable solution. Then the applicant could argue why it was patentable distinct.
- the current SPC regulation suffers from the heterogenity of application by patent offices and
  national courts. As regards the definition of the active ingredient, we believe that it should be
  up to the EMA or national drug agencies to identify if an ingredient of the pharmaceutical
  composition has immunological/metabolic effects that concur to the pharmacological
  effect, and in consequence can qualify as an active ingredient. The ingredient should then
  be identified as active ingredient in the marketing authorization, for legal certainty.
- Despite an apparently large number of ECJ references, the current system works well for most innovative products. Consideration of change should be focused on combination and biopharmaceutical products, in particular vaccines. Some of the other proposals seem to reflect very different policy arguments (such as the "spc manufacturing waiver") and should be separated from proposals aimed at making the existing system work more effectively.
- Comment 1: in case there would be considered a change in the SPC regulation, the
  principles of the Georgetown I decision could at least be taken into consideration in Art. 3.1.b.
  Comment 2: it is critical for the agrochemical sector that a Unitary SPC be developed, in order
  to make sure that patent holders willing to make use of the future Unitary Patent system have
  the certainty that they could also apply for and obtain an SPC having unitary effect.
- No
- Stockpiling: considering it as infringement is a wrong approach. This means a competitive
  drawback for European generic manufacturers: they cannot enter onto the market
  immediately after the expiry of the SPC whilst the non-EU manufacturers can. The SPC waiver
  should cover this aspect as well.
- The PIP extensions and correction of SPC terms are not covered at all
- The granting of SPCs should be reassed. In a context where excessive prices for new
  medicines endanger health systems and encourage the development of rationing policies in
  Europe, the granting of SPCs is running counter basic public health principles that must prevail
  in Europe. The balance between public and private interests and investments urgently need
  to be redress.
- Current system for creating case law by referals to ECJ is too slow and does not provide legal certainty
- Introducing a braodening of article 3 and its interpretation
- The SPC Regulation should not be amended in any way. Any changes to the Regulation will lead to a further period of uncertainty whilst the wording of the amendments is tested by SPC

- applicants through the courts. This will result in 20 years of legal proceedings before the wording of the amendments is clarified.
- Please note that we represent both agrochemicals companies and also producers of active
  ingredients for pharmaceuticals (human and veterinary). However, on Q 10 we could not tick
  both boxes. In addition it is fair to say that out of all companies we represent directly or
  indirectly these are not mainly of the proposed category.
- We wish to comment on some of the questions in the survey where no comments boxes were provided. We use the numbering in the MPI-SPC pdf provided previously by the Allensbach Institute listing the questions. 26a The existence of SPCs is only one factor in deciding where research institutions are located. A high level of IP protection demonstrates that there is a favourable environment for research. It is unlikely to be a coincidence that most pharmaceutical research is located in jurisdictions that provide high levels of IP protection. We do not have generics firms as part of our membership but it is likely that a range of factors influence where generics have their production sites. The presence of SPCs will only be one of these factors. 26b The question on predictability, transparency and quality is, in fact, three different questions rolled into one and is therefore impossible to answer. It is true that, in some cases, the predictability of how offices process an SPC application varies. This could be minimised by the offices cooperating together to produce Guidelines for Examination. These Guidelines could harmonise procedures and be updated as new case law arises. We do not understand how the SPC application process can vary in 'transparency' or 'quality of rights granted.' On SPCs for combination products, there are different types of combination products. As a result of the jurisprudence of the CJEU the SPC system protects some of these combinations well and other combinations poorly, particularly when the combination is a mixture of new and old active ingredients. The SPC system is a significant incentive to develop products which have a short remaining patent life. These products would be uneconomical to develop if SPCs did not exist and patients have benefitted from the introduction of these products. 34 The question is too poorly phrased to answer. We disagree that SPC protection should be directly dependent on the level of investment and effort made to bring a product to market. The system already includes the time taken to obtain an MA as a proxy for this and the length of an SPC is affected as a result. 36 The usage of new antibiotics does not follow the same pattern as other new medicines. New antibiotics should be administered to the right patient, at the right time, and I the right way and so a range of incentives outside the SPC system is better placed to encourage research in this area. The SPC system is not the best tool to encourage further antibiotic research. 37 There are specific incentives for orphan drugs, in the Orphan Medicinal Products Regulation. These incentives have been a notable success as 130 orphan medicines, that might not otherwise exist, have been approved since it was introduced. Although much more needs to be done to treat rare diseases the SPC system is not best placed to assist with this. Other incentives will be more important. 39 We are not aware of the evidence that the pharmaceutical industry is investing more in formulations, delivery systems and combination products than in new molecules, applications and manufacturing methods. The assumption in this question is not, to the best of our knowledge, true for our pharmaceutical members. 44 The proposed definition seems to be an adaptation of the definition in regulatory law. However, it introduces a number of very unclear terms such as 'intended', 'with a view to', and 'on its own'. No doubt this would lead to additional legal disputes. The current SPC Regulation defines the product as the active ingredient of a medicinal product. To define the active ingredient as the product in the proposed definition is viciously circular. 75 To limit unitary SPCs to products authorised by the EMA would be doubly discriminatory. Firstly, only some medicinal products are permitted to seek authorisation via the EMA. Secondly, this authorisation route is not available for crop protection or veterinary products.
- SPCs are critical for innovative pharma industry to keep investing in innovation. The SPC system as it exists today works well, as exemplified by the many SPCs that are being filed and granted. The number of EUCJ referrals is limited in view of this high number of SPCs and SPC applications. Any additional issue can be resolved through further case law and doesn't need any reopening of the Regulation.
- For generic medicines producers, it is of utmost importance to ensure the highest level of transparency in SPC granting procedures. Today some European countries are more transparent than others. Third party observations and oppositions should also be taken more substantially into account.
- The current SPC regulation has evolved over almost 25 years and is in combination with the
  case law a very mature instrument to provide a compensation for the increasing
  development timelines for drugs due to more strict requirements for approval etc. The SPC

regulation is well established and should be kept to avoid new uncertainties through an amended or new version which would need additional 15 to 20 years evolvement. A unitary SPC regulation should be provided in close consideration of the existing one to make the unitary patent a success.

- Definition of 1st MA for new indication of a princeps authorized several years ago for the princeps indication Possibility to protect A with an SPC with respect to MA only refered to add on therapy A + B or B+A (A being a NCE/NBE protected alone or in combination in the patent) Possibility to list the SPC within the regulatory authorites (EMA...) in a kind of "Orange Book like" making the link between Patent/SPCs and MA
- the system is in urgent need for reform and harmonisation. In particular the habit if applying
  for SPCs on different patents and electing late which one will be maintained.
- The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. member companies are the main users of this system, filing and prosecuting SPC applications every day. As such, we would like to provide our impression of the system's operation in general. • The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring new medicines to patients. • As a result, the critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, believes this is not necessary and on the contrary, that a proposal to reopen the SPC Regulation would be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. • First, believes that the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which about 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or denied without any issue. Given the high value of SPCs for innovative biopharmaceutical companies and the fact that SPCs operate in an inherently very litigious phase of a pharmaceutical's life, this number of referrals is not unreasonable. These numbers indicate that, in a vast majority of cases, the Regulation has worked well to compensate the industry for the delays necessary to bring innovative biopharmaceutical products to the market. Within this background, the SPC Regulation has met and is meeting its policy objectives. Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. Believes that, although there will be new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come. • Due to the nature of innovation, further circumstances that may require clarification could arise. However believes that this does not justify amending the Regulation. It is indeed unlikely that these points, or others, could be clarified satisfactorily or comprehensively with a new Regulation and any new provision or wording would inevitably raise new questions for interpretation by the CJEU, especially factoring in the likelihood of disputes inherent to our sector over these valuable rights. would therefore favour retaining the existing Regulation and leave it to the CJEU to clarify pending questions as they arise.

- We support Efpias comments
- The criticism on the current regulation misses the big picture.
- A. Small or midsized companies (and even major Pharma players) do often need and more more time to fully develop a new innovation and bring such innovation to the market. Therefore, the SPC but also the combination of SPC and regulatory Data Exclusivity are critical to convince management and financial stakeholder to invest in the development of a new drug. Major Pharma players do in-license more and more products initially developed by small start-ups and will therefore also acquire/license-in products for which the development has also been slow. For one of our innovation, it was the combination of SPC and Data Exclusivity that helped our company to make the decision to invest in the development of a new drug (which required a long development time). We did consider the combination of these two rights as an acceptable compromise to mitigate business risks. So the SPC is extremely important for our Industry and for patients to ensure innovative drugs are being developed. B. Five years SPC does not mean an additional five years exclusivity as of the marketing approval date: Negotiating a reimbursement price to launch a drug on the market is also a key factor for Pharma Industry (and even more for smaller pharmaceutical companies). One should also keep in mind that Pharma Industry is fully dependent on Public Health Authorities and local Payers. Without an agreement with local Health Authorities/Payers for a reimbursement price (based on a cost benefit assessment by local authorities) for a drug, not Health Care professional will ever prescribe an new innovative drug which is not reimbursement by local Authorities/Payers. No pricing agreement means that the market launch of the product is almost impossible. As such negotiations have to take place in each and every EU member state independently, all these complex post-Marketing Approval pricing processes do also reduce the real Market Exclusivity provided by the SPC (indeed, the SPC extension is calculated as of the 1st EU/EEA Marketing Approval date). For a small company such a process can take between 1-2 years for all EU member states.
- We think that any proposal to create a Unitary SPC should be the object of a separate
  debate and not interfere in the adoption of any legislative initiative aimed to enhance the
  competitiveness of the EU fine Chemical put of the European Union. The discussion addressed
  to the creation of a new EU body to grant Unitary SPCs the adoption of specific rules and
  procedures and the replacement of the current jurisdiction of the EU Member states on SPCs
  should be the object of a different legislative process.
- Art. 15 (1) c of the SPC-Regulation is unclear for nullity actions against SPCs for which the basic
  patent has expired. It is unclear whether in these nullity proceedings one needs to argue
  patentability for the entire breadth of the originally granted subject matter or if one can limit
  the arguments to the product protected by the SPC without having to limit the basic patent
  to this product.
- In some ways, this survey is too simplistic to generate any change regarding SPC. The
  questions are simultaneously too general, and not directed to real solutions if any are
  necessary.
- No
- We align ourselves with the letter and comments sent to you by EFPIA, including in their survey answer if you can identify it.
- I would like to add one comment, for which there is no question in your survey: It has to do with the role of SPCs in the context of the so called Specific Mechanism. This is an instrument of the Treaty to prevent parallel importation from new member states in case the medicinal product at stake could not be protected in that state by a patent or SPC at the time it had obtained such protection in the member state of intended import. The mechanism establishes a notification obligation to originators about the intention to import medicines from a new member state into an "old" one. As an SPC acts in the context of this Specific Mechanism as a trade barrier inside Europe, we would suggest that any decision to award an SPC be entered into a public registry. This would increase transparency and facilitate awareness for the products where this restriction applies, and avoid unnecessary notifications to originator companies when trade is not possible for this reason.
- 1. Given the costly, risky and lengthy R&D cycle, mandatory clinical studies, and the stringent regulatory process that uniquely characterizes the pharmaceutical industry, SPCs form a critical piece of Europe's patent system, without which patent term would often be insufficient

to act as an incentive for innovative R&D. • With an average time to market of 10-15 years, and primary (basic) patents typically filed in the earliest stages of R&D, the normal 20-year patent term would be severely limited and lose much of its value as an incentive absent an SPC 2. The importance of SPCs is further reflected in the fact that every major country with a competitive innovative pharmaceutical sector has a comparable system in place. This includes the US and Japan. • Most other important economies also have a comparable mechanism, including Australia, Russia, Israel, Korea and Singapore (Canada has also agreed to implement an SPC system under the CETA agreement) 3. We are of the view that the existing SPC Regulation fulfills its purpose of restoring a meaningful portion of patent term lost in the R&D and regulatory process, while also including appropriate limits on the amount of term that can be regained. Therefore, it should not be re-opened as a result of the EC review. 4. The CJEU's recent review of certain elements of the Regulation is also not a reason to reopen the Regulation. While some contend that these cases are indicative of a lack of clarity, the evidence shows that the system works well in the vast majority of cases, and can be further clarified by Court decision if and as needed.

- As an overarching point, we suggest current SPC Regulations are not significantly rewritten. For the most part, the law works as intended. Some areas need clarification, and new rights (such as SPCs for medical devices) would be welcomed. However, any substantial amendment of the Regulations is not required and would be potentially problematic.

  Regarding the question "The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the marketing authorisation is obtained" w have interpreted this question to mean that the SPC Regulations act as an incentive to develop new products that might not be developed otherwise; not that the SPC Regulations act as an incentive to prolong the time needed to obtain a marketing authorisation. Regarding the question "The SPC Regulations, as interpreted by the CJEU, sufficiently protect new medical uses of known compounds (second medical use)", we believe the case law (namely C-130/11 Neurim) is moving in the right direction, but we disagree this case is sufficient, because it is not always implemented as set out in section 30 of the Neurim judgement. Regarding the question, "In your opinion, does Regulation 469/2009/EC need to be changed or amended in order to better accommodate biopharmaceuticals and products of recombinant DNA technology?)", we do not believe the Regulations should be changed. Instead, it is the role of case law to develop the legal system in response to technological developments. The European Commission could also issue a communication to clarify the situation. Regarding the statements "The development of new chemical entities requires more effort and investment and thus deserves longer legal protection than... etc.", this is contradicted by many examples, e.g. where a new chemical entity is a naturally isolated product, but requires difficult formulation or derivatization. It is factually wrong to state that all new chemical entities require more (or more important) work to bring to market relative to all other patentable inventions based on known chemical entities. Note also, we have interpreted the term "new forms of existing active ingredients" as "new derivatives of existing active ingredients". Regarding the question "Regulation 469/2009/EC was conceived in view of new molecules, new applications and new manufacturing methods. The pharmaceutical industry is now increasingly investing in new formulations of existing drugs, new delivery systems and combination products", we believe new formulations of existing drugs, new delivery systems and combination products should be eligible for SPCs. However, we do not believe it is necessary to amend the SPC Regulations themselves. Instead, it is the role of case law to develop the law in response to new technological developments. Regarding the statement, "would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC?", we welcome the option for amendment, but this should also include broadening amendments, not only limitation as under Art. 105a EPC, because the right of the SPC is already constrained by the scope of the patent pending when the SPC application is filed. Regarding the creation of a "unitary SPC", it is possible some applicants may find a use for this, but applicants should not be obliged to use a unitary SPC. Applicants should also have the alternative option to obtain national SPCs in the same states.
- While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, we believe this is not necessary and indeed it will be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. Our company strongly supports the existing Regulation leaving to the CJEU to clarify questions as they arise.
- The priority is to create an investment climate that fosters medical innovation that finds tomorrow's cures for the most vexing diseases. Such research improves human lives, reduces the economic impact of disease and creates jobs in the pharmaceutical and healthcare sectors (as well as peripheral supporting industries). SPCs are fundamental to this and reflect

the "lost time" of research, clinical study and regulatory review. In our view the SPC regulation reflects this fairly and adequately. We therefore agree with the position set out by EFPIA on the system's operation in general. • The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring new medicines to patients. • As a result, the critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, believes this is not necessary and on the contrary, that a proposa open the SPC Regulation would be detrimental to the EU competitiveness as a hub for believes this is not necessary and on the contrary, that a proposal to repharmaceutical innovation. • First, believes that the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which about 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or denied without any issue. Given the high value of SPCs for innovative biopharmaceutical companies and the fact that SPCs operate in an inherently very litigious phase of a pharmaceutical's life, this number of referrals is not unreasonable. These numbers indicate that, in a vast majority of cases, the Regulation has worked well to compensate the industry for the delays necessary to bring innovative biopharmaceutical products to the market.

Within this background, the SPC Regulation has met and is meeting its policy objectives. 

Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come. • Due to the nature of innovation, further circumstances that may require clarification could arise. believes that this does not justify amending the Regulation. It is indeed unlikely that these points, or others, could be clarified satisfactorily or comprehensively with a new Regulation and any new provision or wording would inevitably raise new questions for interpretation by the CJEU, especially factoring in the likelihood of disputes inherent to our sector over these valuable rights. would therefore favour retaining the existing Regulation and leave it to the CJEU to clarify pending questions as they arise.

- The SPC is a very important protection right and the system is working very well and is stable for more than 25 years. It meets the objective of the recitals of the Regulation. A change of the system is not required.
- The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. The member companies are the main users of this system, filing and prosecuting SPC applications every day. As such, we would like to provide our impression of the system's operation in general. The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filing of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring new medicines to patients. As a result, the critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and

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- Several of the earlier questions were framed with binary outcomes or no opinion. In general, the situation is more nuanced - I am not convinced that this survey can be of any real value
- We appreciate being given the opportunity to contribute our perspective in this survey. Having said this, we note that the scope of the survey and the level of detail transgress into the realm of legislative activity, for which there are established processes and procedures under European legislation and EU Commission practice. At this juncture, we do not consider legislative activity required. However, should the European Commission, at any point in time in the future, consider legislative activity in relation to the SPC Regulation, we expect to participate in a transparent, unbiased and open stakeholder consultation. As association of the pharmaceutical industry, we deplore the bias and the leading questions contained not once but multiple times in this survey. Pharmaceutical innovation is of primary interest to patients in Europe, and an important economic factor for the European Union. Disparaging the research efforts of the pharmaceutical industry or attempts to curtail the protection of significant investments into research do such interest and that importance unjustice. On a technical level, it is unfortunate that the completed questionnaire cannot be printed for future reference.
- The issue regarding combinations of drug/medical devices which cannot be authorized according to Directive 2001/83/EC. See comments in earlier fields.
- The survey does not provide for the opportunity for an overall assessment of the operation of the SPC Regime in Europe. and vfa member companies are the main users of this system, filing and prosecuting SPC applications every day. As such, we would like to provide our impression of the system's operation in general. The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but

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- Any attempts to "improve" the SPC regulation risk introducing more uncertainty for industry so
  very great care must be taken to avoid impacting upon the incentives to the life sciences
  sector to invest in the long term studies needed before a product can be brought to market.
- As mentioned before packaging and stock-piling has to be allowed during the valid SPC protection!!!
- Most of the issues that the generic industry have with the current SPC regulations are caused by uncertainty in interpretation of the requirements for obtaining an SPC. This is not only as a result of the specific wording of the SPC Regulations, but also as a result of numerous unclear decisions handed down by the CJEU. These decisions often try to solve one issue of interpretation, but end up creating further uncertainty (because they introduce tests which themselves include ambiguous terms), but also because the decisions only go as far as is necessary to answer the specific question that is asked, rather than giving complete guidance. This is exemplified by the numerous referrals around the meaning of Article 3(a) of Regulation 469/2009. In other words, as well as amending the regulations (a subject which the current survey is seeking to address), the CJEU needs to be encouraged to provide decisions which are clearer and which can be applied to real life scenarios without ambiguity.
- No abandonment by the SPC owner possible with retroactive effect. The case law regarding SPCs should be taken into account in its entire and not only in regards to specific decisions. This could be done best via guidelines.
- SPC has broadened the mandate of drug regulatory agencies to allowing expansion of monopoly protections for particular products held by patent holders - an unnecessary and confusing obligation that now rests with drug regulatory agencies. The protection is triggered if a patent has been granted. The SPC has no added value in ensuring quality, efficacy and

safety of medicines, which is the primary and critical function of drug regulatory authorities. It is critical that the current evaluation process include two additional approaches to analysing the SPC: 1. To evaluate the societal costs and impact of enforcement of SPC Regulation, and to introduce an empirical analysis on the implication on the availability and affordability of medicines under SPC protection for public health budgets and as it affects out-of-pocket expenditures. 2. To assess the legality of the SPC regulation, in particular as it relates to an unjustified extension of the mandate of drug regulatory agencies, and secondly, as to the consistency of the SPC regulation with other legal obligations, such as competition law and policy. Preliminary research indicates that affordable generic versions of medicines have been delayed from entering the market in Europe due to SPC protection even though an equivalent product has been available in the global market for around 10 years. This has affected medicines used to treat HIV and AIDS. For example, the patent on the abacavir/lamivudine combination expired in Europe in 2016, but SPC extension has extended exclusivity on the combination until 2019. Generic versions of the product have been available in the global market since 2006. The base compound patent on atazanavir expired in April 2017, with a SPC extension until 2019. A generic version has been available in global market since 2008. The base compound patent of raltegravir will expire in Europe around 2022, with SPC extension till 2023. A generic equivalent has been available in the global market since 2015. Delayed entry of generic version of medicines might have a direct impact on the public health expenditures on medicines, which would be critical for the current survey and evaluation process to tackle with empirical case studies and data collection.

- No abandonment by the SPC owner possible with retroactive effect. The case law regarding SPCs should be taken into account in its entirety and not only in regards to specific decisions. This could be done best via guidelines. Apparently, the focus of this survey is too closely on the pharma sector than other industry sectors. Some of the questions are not entirely clear, including the questions that invite participants to describe their associations. Business associations like X whose members do not come only from the pharmaceutical or agrochemical sector cannot easily describe themselves.
- We agree with various other respondents to the survey who have told us that they think the
  timeframe provided for responses was too short and that some of the questions were not well
  phrased. Further, the multiple choice nature of some of the questions overly simplified the
  incredibly complex issues underlying those questions.
- The survey does not provide for the opportunity for an overall assessment of the operation of member companies are the main users of this system, the SPC Regime in Europe. As filing and prosecuting SPC applications every day, we would like to provide our impression of the system's operation in general. • The necessity of conducting extensive pre-clinical and clinical tests and trials before a new medicine can be marketed, but necessarily after the filling of a patent application covering a new product, means that the biopharmaceutical industry, cannot benefit from anything like the full 20-year patent term to generate revenue to sustain the significant stream of investments required to bring a new product to the market. The critical importance to the innovative pharmaceutical industry of an effective SPC regime is highlighted at Recital 4 of the SPC Regulation, which states that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into that research". This is as true now as when the Regulation was passed. • SPCs were therefore introduced to restore some of the effective patent term, to an overall maximum of 15 years from marketing authorisation. This was done, on the one hand, to ensure sustainable investments into researching and developing new medicines and on the other hand, to preserve the competitiveness of the EU as a research location. • While we understand that there is a certain level of pressure towards re-opening the SPC Regulation to address a number of issues, including the need to accommodate the upcoming unified patent litigation framework and a (misplaced) concern that the number of cases referred to under the Regulation reflects a lack of clarity, believes this is not necessary and on the contrary, that a proposal to reopen the SPC Regulation would be detrimental to the EU competitiveness as a hub for pharmaceutical innovation. • First, believes that the number of referrals to the CJEU is not representative of the otherwise overall good functioning of the SPC Regulation. Around 21,000 national SPC applications for medicinal products have been filed since January 1991 in the EEA countries, among which less than 30 cases (as opposed to more than 100 under trademark law) have been referred to the CJEU and about 90% have been granted or denied without any issue. Given the high value of SPCs for innovative biopharmaceutical companies and the fact that SPCs operate in an inherently very litigious phase of a pharmaceutical's life, this number of referrals is not unreasonable. These numbers indicate

that, in a vast majority of cases, the Regulation has worked well to compensate the industry for the delays necessary to bring innovative biopharmaceutical products to the market. Within this background, the SPC Regulation has met and is meeting its policy objectives. • Though the vast majority of SPCs have been sought and obtained within the clear ambit of the Regulation, questions have arisen regarding the correct scope of SPC availability for more complex product situations stemming from evolutions of the biological and biopharmaceutical sciences. It is natural and appropriate for national courts to seek clarification and interpretation of EU laws with regard to these. These questions have however been gradually addressed by the CJEU, which has clarified in its decisions a very substantial number of these points which were raised to it. believes that, although there will be new referrals from time to time where issues remain, these are likely to concern only a very limited number of cases. It would further be unrealistic to expect the text of the Regulation (or any new legislation) to anticipate or even keep up with all developments to come. • Due to the nature of innovation, further circumstances that may require clarification could arise. However believes that this does not justify amending the Regulation. It is indeed unlikely that these points, or others, could be clarified satisfactorily or comprehensively with a new Regulation and any new provision or wording would inevitably raise new questions for interpretation by the CJEU, especially factoring in the likelihood of disputes inherent to our sector over these valuable rights. would therefore favour retaining the existing Regulation and leave it to the CJEU to clarify pending questions as they arise.

- Survey touches only sensitive Points, it lacks an overall assessment.
- Question 39 on new formulations, delivery systems and combination products does not allow any comments, so here a comment in detail. The question implies that an amendment is necessary. This is not the case. The current SPC Regulation can be adequately applied to recognize such investments, as evidenced by the CJEU Neurim case on a new formulation of an active ingredient that had been authorized before. The questions 58 and 59 on product definition do not allow comments, so here a comment in detail. The questions are apparently based on a misunderstanding. The product reference (not definition) is for convenience only and has no legal effect. The scope of protection of an SPC is based on a) the basic patent and b) the marketing authorization. The product reference does not come into play at all, it is legally irrelevant, and for convenience only. Question 65 does not allow to comment, either. It is not clear why a question on Bolar exemption is included in the SPC Survey. This is off topic.
- Referring to Q 75: The plant protection industry advocates for a quick introduction of a unitary-SPC for plant protection products. Only through the introduction of such a unitary SPC for this area it can be ensured that the advantages offered by the new European patent system could be used by the companies. Due to the high investments in the research and development of their innovative products, companies rely on effective protection through SPC. The missing possibility to obtain a unitary SPC leads to a significant gap in the protection of intellectual property in Europe. Without the opportunity to obtain a unitary SPC there is a high risk that companies in the plant protection sector will not or only reluctantly use the new system and the associated advantages will remain unused. It is, therefore necessary to create a unitary SPC by means of a separate regulation until the first European patent with unitary effect is granted. In the absence of a centralized authorization procedure for plant protection products, the unitary SPC should be granted based on the EU-wide approval of the active ingredient by the first authorization in a Member State. It should have unitary effect in those Member States who have granted product-authorizations regarding their own territory for the same product as the first authorization granted by a first Member State at the expiry date of the basis patent. General: The focus of this survey is very close to the pharma sector and does not take the specific questions which are raising in the plant protection sector enough into account. We are of the opinion that some of the questions are not entirely clear, so that the answers which were given by us in this survey rely in a noteworthy number on our interpretation of the precise content of the question.

## Q 77: If there is anything else you would like to suggest or tell us in connection with this survey, please feel free to do so now:

 would like to express our concerns regarding the way in which this important survey is being conducted and the consideration given to users' views, i.e. views of those companies which file and prosecute SPC applications and rely on the protection that SPCs provide to invest substantially and sustainably into research and development. Not only were industry association stakeholders given very limited time (11 working days effectively), but also the formulation of the questions does not lend itself to allow for a thorough reflection of the whole spectrum of views of stakeholders. In relation to question 35, the UK and European bioscience sector has been and continues to strongly support the use of market incentives to increase investment in the development of new antibiotics. However, we do not believe that the SPC regime is an appropriate mechanism to achieve this. Industry is working with the authorities to explore the most effective means to achieve our shared goals and we urge all parties to continue in this approach.

- For early stage technology such as gene therapy that is showing promising results for treatment of rare diseases, it is key to encourage investment by providing certainty of protection of the IP while insuring the access to treatment to the patients. Improvement of existing production process is crucial to insure affordable prices for the patients. Ensuring IP protection for the production process of a gene therapy treatment is therefor important..

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  In the production process is crucial to insure affordable prices for the public generosity and by partnership with some pharma companies (licensing-out, research collaboration). We encourage initiative that provides certainty for investors and in the meantime ease access for the patients to innovative treatments
- We are fully aware of the comments made by EFPIA and our comments and views are
  entirely in line with those as set out in EFPIA's response to this survey. However, we do not feel
  the need to repeat EFPIA's comments.
- The last question on EMA was answered in the negative, because there is no EMA available for crop protection SPCs
- FICPI (the international federartion of IP attorneys in private practice) has provided a reasonable position paper regarding UP-SPC and the urgent need to establish a UP-SPC system from the very beginning of the UPC system. A patent-driven and innovation-rewarding UP-SPC system would be a big incentive for the UP/UPC system and possibly (for EP holders) a decision point to refrain from "opting out" (if the UP-SPC system is available for EP holders (at least for an appropriate transition period)).
- we would recommend highlights the fact that questions are biased and some even ignore the very purpose of the SPC. For instance, the question of whether SPCs encourage evergreening or whether they encourage companies to increase the time span between preclinical phase and regulatory filing seems very biased and misplaced. Similarly, the link between the SPCs and the development of antibiotics or orphan medicines is misguided. While antibiotics were not developed for different reasons (including the downward pressure on demand due to AMR), orphans have a specific set of incentives, which work well. Revising the SPC Regulation would not bring any improvement in that respect. Moreover, the questions are in a multiple-choice format with very binary answers, which fail to capture the complexity of the issue. While it is sometimes possible to add some comments to put answers into perspective, many questions do not provide for that possibility, which raises questions about the potential misinterpretation of the answers, therefore affecting the quality of the output and ultimately its subsequent use for policy-making.
- It would have been helpful to have provided more comment boxes, as the topic is a very complex one. Even more preferably, a better opportunity for a face-to-face discussion would have been appreciated. It is difficult to capture all of the nuances of this issue in a simple online survey.
- The focus of this survey is very close to the pharma sector and does not take the specific questions which are raising in the crop protection sector enough into account. As to the fact that represents both pharmaceutical and crop-protection companies, we answered the questions from the viewpoint of the pharmaceutical industry and added comments from the viewpoint of the crop protection companies where possible and necessary. Furthermore we are of the opinion that some of the questions are not entirely clear, so that the answers which were given by us in this survey rely in a noteworthy number on our interpretation of the precise content of the question.

- We do have serious concerns over the form of questions in this survey. Many appear to be biased towards a particular response or have many factors or assumptions built in which cannot be addressed in a multiple choice format.
- Many questions are unbalanced, seem to be based on assumptions that are misguided and do not provide fair and/or appropriate options for answers.
- Great efforts should be made soon in order to implement CJEU-decisions of the last decade in terms of SPCs and a new framework should be established which is clearer as the current SPC-Regulation and does (as a consequence) not leaf so much uncertainty an "room for legal disputes"
- SPC waiver should also permit stockpilling, assuming that no entry in the market can take
  place before expiry. This could contribute to decrease costs of generic drugs (simpler supply
  chain, less transportation costs)
- In certain sections, the design of the survey does not lend itself to eliciting useful responses. This particular applies to those questions where: the options for responding are very limited (and not necessarily reflective of the full range of possible views); there is no "other" option (with a comments box to explain that option); and/or there is no ability to provide comments upon the reason why a certain option has been selected.
- We refer to EFPIA's cover letter to their response to this questionnaire.
- no
- Apparently, the focus of this survey is too closely on the pharma sector that crop protection industry. Some of the questions are not entirely clear.
- Nice work so far!
- This survey has been very poorly drafted and poorly administered. The time period for response (despite the extension) has been too short, particularly in view of the very long time it took to receive the survey. No single person within a company or institution knows all of the answers or consensus opinions of their company/institution, and to take the time out of our regular business is very difficult, particularly given that our business truly is time intensive when trying to develop new medicines and get them to patients as quickly as possible). Making our response even more difficult was the poorly written questions. Too many of the questions made assumptions that were not correct or were opinion, not fact. Too many answer choices were too limited and lacked an opportunity to comment. Many of the questions demonstrated ignorance about the purpose of the SPC Regulation and the nature of the bio/pharmaceutical industry. By way of example, the three questions regarding "how do SPCs and patents relate to your research activity" were nearly nonsensical. One does not conduct "freedom to operate searches" on "granted patents or patent applications." You conduct a "freedom to operate" search on a product, and to the degree you find a patent or patent application that may pose a risk to your freedom to make, use and sell a product, you take note of any SPCs because they extend the term of enforceability of that product. With respect to "consulting patent applications or patents as a source of information for research," that is certainly one of the important functions of patents/patent applications - to inform those of skill in the art of a new invention so that they can learn from and improve upon it. However, patents and patent applications are, in this regard, like any other scientific publication - information about the progress of science from which a reader may derive a new invention. Another example of a question that suggests a lack of understanding of the industry and laws related thereto were nearly all the questions related to the Bolar exemption. The Bolar exemption has nothing to do with SPCs. It is an industry-unique exception to liability for infringement of patents - permitting certain infringing activities to be conducted without liability, if those activities are necessary for and done for the purposes of obtaining regulatory approval of a medicinal product. Similarly, orphan drug exclusivity and issues related to the lack of investment in new antibiotics should not be in a questionnaire about the legal effects of SPCs. Orphan drug protections stimulate investment in medicines to treat orphan disease, and the incentives have worked exactly as intended. The fact that new, more potent antibiotics are need and at the same time they must be used very sparingly, requires completely different incentives than an SPC and likely even different from extended regulatory exclusivity. An example of a question that made erroneous assumptions and lacked a comment box for explaining one's answer, was the following: "The development of new chemical entities requires more effort and investment and thus deserves longer legal

protection......compared to the development of new forms of existing active ingredients;....compared to the development of new formulation of existing active ingredients; .....compared to the development of new indications for existing active ingredients." This question assumes that the level of "effort and investment" required to engage in the enumerated activities is consistent within each activity. Of course, it is not. It also assumes that the differences in levels of "effort and investment" both can be determined and will be significant enough that different periods of legal protection are appropriate. To what type of "legal protection" and "longer" than what periods of protection are left to the reader's interpretation. There are numerous additional examples of bias, erroneous assumptions, unclear wording, etc. in the survey, but since the deadline for submission is hours away, and I have already spent a full day filling in the survey (after many days of reviewing, researching, considering and discussing the survey questions and our answers), I will stop here. (Except for one more question - how in the world could my age possibly be relevant to analysis of this survey, the answers to which, supposedly, reflect a corporation's collective viewpoint?!)

- I have serious reservations about the content and nature of this survey. It seems to be have been written from the point of view that the current Regulation requires substantive amendment, which is not the case. The question implying that SPCs play a role in 'evergreening' was astonishing to see and extremely troubling. The wording of many questions was unclear and others simply did not make sense, hence it was difficult to answer or comment on these without having to guess or assume what the question related to. For example the statement 'The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the MA is obtained' does not make any sense.
- It was clearly overly focussed on Medicinal SPC regulation, which made it sometimes difficult for us to answer the question
- Question 18 does not allow numbers above three digits. The correct number for our company is 1.223. Presumably the number for most medium to large pharma companies which have and have had products put on the market throughout the EU over the last 10 years will also exceed 1.000.
- Many questions in this questionnaire are unclear or appear to be biased. Other questions appear to have been created in misapprehension of how pharmaceutical companies work. So it is altogether questionnable whether the this Survey will be able to fulfil its purpose and give a clear and undistorted picture (resulting from posing unclear and biased questions in the first place). Moreover, the Deadline given to answer this extensive and very important questionnaire although extended at the last minute was far too short. Also in this context, the Comments to be provided by the EFPIA to the MPI by letter are highly relevant and to be regarded.
- The extension of time was welcome since the initial time period for response was too short to prepare a well thought through response. In part, the questions were unclear/not sufficient specific. Especially were only tick boxes were provided a qualified response was not always possible as in such cases it was not possible to provide comments. Many questions were trying to push into a certain direction. Again, since it was not always possible to provide comments, a qualified response was difficult, particularly were multiple factors drive a decision, which often may be case-by-case.
- As a general point we believe that using a questionnaire of this nature (with a limited number of potential answers and no opportunity to comment in many cases) to obtain views on this very complex subject is too inflexible and does not give the opportunity to express the nuanced and complicated views that are held by our members. As such it is not appropriate to rely on the results of this survey as a basis for any future decisions or policies in relation to SPCs. In addition, the short timescale originally provided for completion of the questionnaire, combined with the lack of a definitive hard copy version, made it extremely difficult for our organisation to discuss and obtain views from our members. Certain of the questions appear to be poorly worded or capable of more than one interpretation, which could lead to two different answers. Furthermore some questions appear to be based on assumptions with which we would not necessarily agree, making them difficult to answer. For many questions, the simplistic answers provided could be misleading without further comment; we have therefore sometimes been forced to answer 'no opinion' or 'impossible to say' because there was no answer that adequately reflected our views.

- Several of the responses were "No opinion / Impossible to say". These are very different answers and must be reflected properly in the report and not mischaracterized as "no opinion". Also, it is incredibly unhelpful not to provide a full and transparent set of the questions in the survey that can be considered as a whole when answering, and to provide a system which does not allow the review of past answers without losing all intermediate answers. That significantly undermines the ability of organisations to consider and discuss views on difficult questions of policy.
- If you should need some examles of "problematic" SPC are statistics on SPCs please contact
  me
- The way certain questions are formulated makes it difficult to contribute. For, instance, we believe that the development of new chemical entities require far more effort and investment that the development of new formations, new indications, etc. We believe that there should not be SPCs for new formations, new indications, etc. And not only that there should be shorter SCPs, which our response to the question could leadt to believe considering the way the question is ask.
- This was a good questionnaire!
- To confirm, this survey is completed in my own personal opinion and not as representative of the broader views of my law firm.
- I agree with all comments made by EFPIA on this survey.
- Some of the questions are ambiguous and would have needed more clarification. Therefore, a comment field for each of the questions would have been helpful to explain the rational for certain answers.
- The statements in auestionon FTO searches are unclear and show a lack of understanding of pharmaceutical companies' iterative and complex research and development processes and of their daily operations. Similarly, the answers to question 25 on how we procure APIs will depend on the type or phase of a research project. All of the answers will typically apply to a large research-based company, albeit to different projects at different times and for different reasons. We do not see how an amendment to the SPC Regulation could help overcome the alleged deficit of investments into the development of antibiotics. This proposal further shows a misunderstanding of the pharmaceutical industry and in particular of the difficulties and issues associated with antibiotics development, which point to the importance of effective and efficient incentives, taking into the specific challenges associated with antibiotics, in particular that these are expected to be prescribed as rarely as possible or to be reserved for late-line use. These constraints on the use of antibiotics limit the efficiency of traditional incentives (patents, SPCs) and exemplify the consequences of a lack of efficient incentives. Similarly, question related to Orphan Drugs seems to ignore the existence of the Orphan Medicinal Products Regulation, which was specifically designed to address insufficient investment in the development of medicines for rare diseases. The Orphan Regulation has been a notable success. Of course more research and hence more investments are needed, as 130 orphan medicines have been approved up to today and many of the 6-7,000 rare diseases still lack effective treatments. However the Orphan Regulation has significantly encouraged investments since 2000, in an area that was lacking treatments. If there is insufficient investment in some areas, societal priorities and poor knowledge about the nature of some rare diseases are the most common reasons for that - it has little, if anything, to do with SPCs. Changing the SPC Regulation would in no way impact orphan medicine development, as orphan medicines development relies on specific mechanisms provided by the Orphan Medicinal Product Regulation, recognising that for such diseases, as for antibiotics, traditional IP incentives are not sufficient. We strongly believe that the creation of a unitary SPC is necessary and suupport the porposal that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist - this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these

needs would be relatively light. This is a logical continuation of the Member States' decision and agreement to create a European Patent with unitary effect. This only requires the necessary institutional provisions i.e. a granting authority and procedure, to be provided for. These should be jointly applicable to Regulations 469/2009 and 1610/96. As the SPC "shall confer the same rights as conferred by the basic patent", a SPC based on a unitary patent would simply have the same effect as a unitary patent. The decisions made by the body granting unitary SPC, e.g. not to grant a SPC, should be appealable within a court system, preferably one that has expertise in patent law, such as the Unified Patent Court. It must also be possible for questions on points of law under the SPC Regulation to be referable to the CJEU. As for current SPCs, unitary SPC should be available based on a European patent with unitary effect and a marketing authorisation, irrespective of whether it is centralised and granted by the EMA or national and granted through the decentralised or mutual recognition procedures. If unitary SPCs were to be available only to products granted through the centralised procedure, it would unduly discriminate against certain products which are not eligible for the centralised procedure. In the scenario where a product has not been approved in all Member States, the unitary SPC would then only be enforceable in these countries were a marketing authorisation has been granted.

- would like: to stress the great importance for the pharmaceutical industry of the SPC regulation, and accordingly the great importance of the questionnaire, to express regret over the very limited time provided for responding to the many and complex questions. received the questionnaire on June 13, with response due June 23. This gives us only a few working days to answer, to express concern for the way in which some questions in the survey are drafted, for example lacking clarity and balance, which made them very difficult to respond to, to express that in these circumstances has largely had to rely for its response on work done by EFPIA, the European Federation of Pharmaceutical Industries and Associations.
- Some of the questions should have been expressed in more detail to avoid misunderstandings and being unbalanced.
- Why questions about my age? Several questions are unclear and don't specify the background of the question or don't clearly define critical terms/words used in the question.

  Other questions highlight that there is a lack of understanding of the development process in the pharma industry e.g. questions 24, 25, etc or lack of understanding of the SPC/Patent system e.g. question 57. - Many questions are orientated (based on pre-defined assumptions) and don't give us the possibility to provide a background or explanation to our answers or challenge our pre-defined assumptions e.g. question 26a. - I have also noticed questions not at all related to the SPC legislation and its purpose, such as the "surpising" link between SPC and the concept of "evergreening" (question 31), which is obviously either a misunderstanding of the SPC system or a "politically orientated" question going beyond the objective of this project and need of "objectivity". Surprisingly we were not even given the possibility to fully reject your proposal/statement by answering "No" or "Not at all". This is an orientated question with oriented answer that can be shocking for an expert. opinions about Pharma Industry: A few words about common misconception statements, we can read more and more in the medias or social medias, against Pharma industry and the Patent system. One should first keep in mind that Pharma Industry is today fully dependent on local Public Health Authorities and local Payers. Without an agreement with local Health Authorities/Payers for a reimbursement price for a drug (based on cost-benefit assessment performed by local authorities), not health care professional will ever prescribe a new innovative drug which is not reimbursement by local Authorities/Payers. No "pricing agreement" means that the market launch of the new drug is almost impossible. Over the last ten years I have noticed an increasing risk aversion in the pharma sector, because expected sales are very often not achieved, expected sales prices is most of the time much lower than originally foreseen (due to very strong pressure on healthcare budgets - although the drug costs in the total healthcare costs (Hospitals, etc.) is very low). Furthermore in the Pharma sector, the Public Healthcare authorities do actively promote the market entry of generic products/copies, and do ensure a strong price drop takes place after the original product/basic patent expires. Public Healthcare authorities do stimulate fast and strong generic competition by "incentive" policies e.g. oblige pharmacies to substitute the prescribed drug with the cheapest product. Therefore, in such challenging environment, having an acceptable market exclusivity (Patent, SPC, Data Exclusivity) is becoming more and more critical for innovators. If you compare the share price of big pharma players with e.g. big technology players over ten years, you can easily see that investors don't invest so much into pharma Industry anymore because of the increasing risk profile and lower predictability. The ten years share price is probably the best evidence against all the

misleading statements we can read against our industry and against exclusivity rights covering drugs.

- No.
- We wish to add some comments on questions where no comment boxes were provided. Over the last 10 years we have likely filed in the order of 1000 SPC applications. In the human health area we will normally file for SPCs in all EU member states. Coverage will be less in the animal health area. Our patents in the human health area are obtained by the EPO and so their geographical coverage will be greater than just the EU. Our human and animal health divisions market products throughout the world, not just in the EU. It is not possible to answer whether national patent offices differ in terms of predictability, quality and transparency. This is three questions rolled into one. There is little problem with predictability. We do not know what it means to ask whether one SPC application procedure is more transparent or of higher quality than another. Under CJEU case law SPCs are available for combinations of new active ingredients where there is an appropriate basic patent. This is also true for combinations of new and old active ingredients but the case law limits the circumstances in which this latter category of combinations can receive an SPC. The CJEU in Neurim has affirmed that new SPCs are available for new uses of old active ingredients providing there is an appropriate basic patent and new marketing authorisation. There is currently variation between national patent offices over how to apply this decision if the earlier and later uses are both in humans. It would be good to incentivise new uses for old active ingredients generally. We do not think the length of SPC protection should be directly dependent on the level of investment and efforts in bringing a new product to market. This is already taken into account via the proxy of the time taken to receive a marketing authorisation which determines the length of an SPC. The SPC Regulations are not an appropriate mechanism for encouraging investments in antibiotics which need to be useful for many years in medical practice and only used with the right patient at the right time. Other incentives are more suitable such as can be found in national reimbursement systems. Product is currently defined, under Art 1 of the Regulation, in terms of the active ingredient. Introducing a definition of the active ingredient in terms of the product would be viciously circular. in addition the proposed definition includes unclear terms such as 'intended', 'with a view to' and 'on its own' which would lead to many legal disputes. Requiring product definitions in the form of patent claims would lead to very variable results on the same application in different offices. Further, some offices do not currently examine for inventive step on national patent applications and do not have internal expertise to assess patent claims. Many legal disputes would follow if such a product definition was required. We have significant manufacturing in Europe. Where we plan to make products that contain a third party active ingredient we respect SPC rights in deciding on the manufacturing location. There are questions on the scope of the Bolar exemption for patents that will be under the exclusive jurisdiction of the Unified Patent Court. This scope may be narrower than presently allowed in many national laws. We would welcome an amendment of the Medicines Directive to broaden the Bolar exemption to cover clinical trials and Healthcare Technology Assessments. A unitary SPC should not be limited to applications based on centralised MAs. This would be discriminatory as not all products are eligible for centralised approvals, nor do veterinary products have a centralised approval process.
- We have concerns with how this survey was conducted and refer you to the EFPIA comments in this respect.
- Process-wise, while the deadline to answer has been extended, we found that a three-week (11-working-day) term to reply to a questionnaire of this importance was highly unrealistic. The suggestion that 40-60 minutes would be enough to answer the questionnaire was completely unrealistic since (a) some questions need data to be generated: (b) responses needed to be proposed, evaluated and determined by various teams and (c) many questions were so unclear and the options for answers so inappropriate or inappropriately limited that they required long discussion, sometimes of the meaning of the questions, before answers could be agreed within individual companies.
- The significance of the SPC system should have been better reflected in the way how the study was procured: After having announced the study to come early in 2017 it was delayed several times and when it came finally the time for answering was too limited. The quality of questions and answers were inappropriate. Some questions were imprecise, at other occasions the options for answering were not balanced or incomplete and some questions/answers were inappropriate in view of the complexity of the pharmaceutical research and development process. More comment fields for clarification would have been of advantage.

- Try and draft a decent survey? But really this is an issue which does not fit well into a survey format. Actually, the SPC system works well most of the time, particularly for single ingredient products. The ECJ has resolved some of the issues relating to combinations, but has also created (quite unnecessarily) some new ones.
- The deadline for replying to survey was too short, even with the extension. Several questions are not clear and ought to have been validated by experts in SPC and pharma R&D. Some questions lacks objectivity and don't have a sound basis. For example the question concerning "evergreening" practices with no definition of the term.
- We would welcome a "save" ability on this questionnaire.
- Apparently, the focus of this survey is too closely on the pharma sector than other industry sectors. Some of the questions are not entirely clear.
- The survey should take a broader cross-disciplinary approach by looking not only at the legal
  and economic implications of SPC regulation, but more importantly the survey should
  examine the implications and costs to society of the regulation in particular upon public
  health agencies and patients in terms of the availability, accessibility and affordability of
  medicines in Europe.
- Business associations like \_\_\_\_\_\_ whose members do not come only from the pharmaceutical or agrochemical sector cannot easily describe themselves in the introductory part of the survey. \_\_\_\_\_\_ is the leading advocate for growth and competitiveness at European level, standing up for companies across the continent and campaigning on the issues that most influence their performance. A recognised social partner, we speak for all-sized enterprises in 34 European countries whose national business federations are our direct members.
- - Time to reply too short some questions ambiguos
- We appreciate the opportunity to contribute our perspective. However, we are concerned about the approach. In many instances, the survey is framed as a specific legislative proposal. That is not the methodological purpose of a survey. We are concerned about a misuse of due process in view of EU legislative processes. We do not consider changes to the SPC Regulation required. In case the European Commission, at any point in time in the future, considers proposals for an amendment, we a transparent, unbiased and open stakeholder consultation. We note that quite a few of the questions are biased and/or leading. Furthermore, it is not clear why the answers are often presented in stark contrast of "favor"/"oppose" why was there no option to indicate "we do not consider a change required, the SPC Regulation works well as it is"? Last not least, why can the questionnaire not be printed? That is standard in such surveys.

#### \$3: What position do you hold at your office/firm?

- Senior patent attorney
- Senior IP Counsel
- IP
- Head of IP -
- Patent Attorney
- Patent Attorney
- Senior Patent Attorney and shareholder
- Associate GC
- Employee in managerial position.

- Technical
- Legal consultant.
- Head of IP
- IP Head
- Vice-Director responsible for IP related policy developments

#### \$ 10: What position do you hold at the association you represent?

- Policy and Project Manager
- Director IP Policy
- member of the board, head of SPC working group
- Legal adviser
- Head Public Affairs
- Chair of the relevant working group
- Legal Counsel
- Head of Foreign Trade policy
- chairman of the legislative committee of the czech generics association
- Rechtsanwalt (Syndikusrechtsanwalt)
- Legal and Regulatory Manager
- President
- Public Affairs Director
- Lawyer
- Head legal
- Anti-Counterfeit & Legal Affairs Manager
- Council Member
- Fellow
- regulatory and legal affairs manager
- CEO
- MANAGING DIRECTOR
- European Public Affairs Consultant
- Manager (Responsable plaidoyer et mobilisations citoyennes)
- Member.
- In-house lawyer specialized in IP
- President
- Director

- Director General
- Senior Advisor
- Director
- Director European Affairs
- Director of Legal, Fiscal & Compliance Affairs
- Head Legal Adviser
- Legal Counsel
- co-President of the Patent Commission of the professional association of French patent attorneys (CNCPI)
- Lawyer
- Counsel, Law Department
- Former President; member of Advisory Board.
- Head of the IP committee.
- Senior Legal & Policy Advisor
- Senior Adviser
- member of presidium, Treasurer
- Director Pharmaceutical Industry

#### \$ 11: What position do you hold at the university or research institution you represent?

- Technology Transfer
- Director patent center
- University professor
- Technology Manager
- Senior researcher at the University Medical Centre with a background in law.

Institut für Demoskopie Allensbach Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU			

## 5 Appendix

- Survey data
- Sample structure
- Composition and structure of the universe and sample
- Printout version of the online questionnaire
- Data concerning the accuracy of representative surveys

# SURVEY DATA for the online survey among stakeholders of the SPC system

Overall responsibility

Institut für Demoskopie Allensbach GmbH

for methods: Radolfzeller Strasse 8

78476 Allensbach/Germany

**Project manager:** Dr. Anne Niedermann (Director, Surveys for legal evidence)

Target group interviewed (universe):

Stakeholders from the 28 EU Member States who deal with Supplementary Protection Certificates (SPCs): companies active in the pharmaceutical sector, industrial or professional associations in the pharmaceutical sector, law firms or

patent law firms, along with universities and research institutions Appendix (II) provides more detailed information on the definition and

composition of the universe from which the sample was drawn.

**Type of interview:** Online survey

Each of the stakeholders selected for the survey was sent an email inviting him/her to take part in the survey. The email contained a link leading to the online

questionnaire along with a personal codeword. By employing personal codewords, it was ensured that only the stakeholders selected could complete

the questionnaire—and that they could do so one time only.

**Interview length:** The median interview length was 40 minutes.

Note: The interview length was measured from the time when the online questionnaire was first opened until the time when the response to the last question was entered. To make sure that the average interview length was not erroneously inflated by a few individual interviews that were interrupted and then continued at a later point, the median length was ascertained instead of the mathematical average: this means that 50 percent of the interviews took less or the same amount of time to complete, and 50 percent of the interviews were completed in the same or a longer

amount of time than the median value.

**Dates of fieldwork:** May 22 - June 23, 2017

Sampling method: The survey was a complete survey of an address file provided by the MAX PLANCK

INSTITUTE FOR INNOVATION AND COMPETITION.

The address file was compiled from the following sources:

- National registers of SPC holders

- The EU Commision's list of marketing authorisation holders

- Membership lists of various industry associations.

# SURVEY DATA for the online survey among stakeholders of the SPC system

Number of respondents/ response rate for the net sample:

Of 311 addresses employed, a total of 203 completed interviews were realized, resulting in a gross response rate of 66 percent. Two reminders asking respondents to complete the questionnaire were sent to each email address. Additionally, the first reminder was sent to the postal addresses that participants had provided.

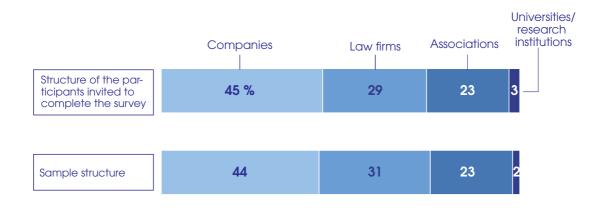
		Total n	Companies n	Law firms	Associations n	Universities/ research institutions n
Gross sample	= Selected stakeholders	311	138	91	72	10
Dropouts (neutral)	Undeliverable emails	4	3	-	-	1
Net sample	= Gross sample minus dropouts	307	135	91	72	9
	Confirmations (receipt of invitation confirmed, including out-of-office messages)	134	65	33	36	5
Non- responses (non- neutral)	Explicit refusals	6	1	1	3	1
	No information available (no feedback at all)	76	34	24	18	3
	Break-offs (interview started but not completed)	22	11	3	5	0
Interviews	Completed interviews	203	89	63	46	5
Response rate	as a percentage of the net sample	66%	66%	69%	64%	56%

## COMPOSITION AND STRUCTURE OF THE UNIVERSE AND SAMPLE

a) Structure of the participants invited to complete the survey (universe) compared to the survey sample achieved (sample structure)

	Structure of the participants invited to complete the survey		
	n	%	
Companies	138	45	
Law firms	91	29	
Associations	72	23	
Universities	10	3	
TOTAL	311	100	

	Sample s	tructure	Sample struc participant subsec	s accepted
	n	%	n	%
Companies	89	44	85	45
Law firms	63	31	58	31
Associations	46	23	41	22
Universities	5	2	5	2
TOTAL	203	100	189	100



## COMPOSITION AND STRUCTURE OF THE UNIVERSE AND SAMPLE

### b) Sample: Respondents by country<sup>1)</sup>

	Structure of participants invited to complete the survey	Share in total sample	Share in total sample without partici- pants accepted subsequently
	%	%	%
Germany	24	18	18
United Kingdom	11	9	9
Spain	9	10	9
France	8	8	8
Italy	6	5	5
Other EU Member States	32	28	28
Other countries	10	23	22
TOTAL	100	100	100

### c) Sample: Response rates by country<sup>1)</sup>

	Response rates/country
	%
Spain	70
France	61
Italy	54
United Kingdom	50
Germany	48
Other EU Member States	56
Other countries	139 <sup>2)</sup>
TOTAL	64

 $<sup>^{\</sup>hspace{-0.1em} \text{\scriptsize I}\hspace{-0.1em} \text{\scriptsize I}}$  Without law firms, since they were asked a different question

<sup>2)</sup> Due to participants accepted subsequently

### INSTITUT FÜR DEMOSKOPIE ALLENSBACH

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### MPI - SPC Online Survey 3754 / Final

Thank you for your interest in the present survey on the experience and perceptions of stakeholders regarding the functioning of the European system of Supplementary Protection Certificates (SPCs).

This survey is part of a study being conducted on behalf of the European Commission by the Max-Planck-Institute for Innovation and Competition. The questions cover how the SPC system currently functions, as well as some possible changes which may be considered for the future.

We understand that various stakeholders have different levels of experience with this topic. While we hope to receive answers to all of our questions, there are some questions that you may skip, should you feel that your knowledge and experience do not allow you to give a well-founded response.

In any case, we truly appreciate your very valuable support in providing an empirical basis for our study.

### Q.1 Which of the following applies to you? [One response only]

### I represent a ...

Company [= definition 'company'] [ --> Go to Q.2]
 Association [= definition 'association'] [ --> Go to Q.7]
 Law firm or patent law firm [= definition 'law firm'] [ --> Go to Q.13]
 University or research institution [= definition 'university/research'] [ --> Go to Q.16]

["No response" is not an option here, since the question functions as a filter]

[If definition 'company']

Q.2 In which country is the company entity you represent located? Please select the country from the drop-down menu. [One response only]

[Drop-down list of European countries, in alphabetical order]

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Luxembourg

Malta

The Netherlands

Poland

	Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom
	[Small text box]
	Other country (please specify):
	[NO RESPONSE] [All answers> Go to Q3]
If de	finition 'company']
Q.3	Is the company entity you represent active in a field for which SPC (Supplementary Protection Certificate protection is available? [One response only]
	Yes [> Go to Q.4] No [> Go to Q.40] [= definition 'company not active in any SPC field']
	["No response" is not an option here, since the question functions as a filter]
If de	finition 'company']
Q.4	What is your company's sector of activity? [Multiple responses possible]
	Pharmaceuticals (humans) Pharmaceuticals (animals) Plant protection
	[If one single response is given for Q.4> Go to Q.6] [If multiple responses are given for Q.4> Go to Q.5]
	["No response" is not an option here, since the question functions as a filter]
If de	finition 'company']
Q.5	What is your company's <u>main</u> sector of activity? [One response only]
	Pharmaceuticals (humans) Pharmaceuticals (animals) Plant protection
	[NO RESPONSE] [All answers> Go to Q.6]
If de	finition 'company']
Q.6	Would you describe your company as being <u>predominantly</u> a research-based company ("originator") or a generic company? [One response only]
	Originator [= definition 'originator company'] Generic [= definition 'generic company']
	["No response" is not an option here, since the question functions as a filter]  [ All answers> Go to Q.18]

[If definition 'association']

Q.7 What type of association do you represent?

[One response only]

Industry association [= definition 'industry association']
Professional association [= definition 'professional association']
Other association [= definition 'other association']

[ All answers --> Go to Q.8]

[If definition 'association']

Q.8 In which country is the association you represent located? Please select the country from the drop-down menu. [One response only]

[Drop-down list of European countries, in alphabetical order]

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Luxembourg

Malta

The Netherlands

Poland

Portugal

Romania

Slovakia

Slovenia

Spain

Sweden

United Kingdom

[Small text box]

Other country (please specify): .....

[NO RESPONSE]

[All answers --> Go to Q.9]

[If dej	finition 'association']		
Q.9	How many members does your association	have?	
	[Small text box]		
	Please enter number: members	[NO RESPONSE]	[All answers> Go to Q.10]
[If dej	finition 'industry association']		
Q.10	Does your association <u>mainly</u> represent pha [One response only]	armaceutical companies o	r companies from the agrochemical sector?
	Pharmaceutical companies [> Go to Agrochemical companies [> Go to	Q.11] Q.26]	
	["No response" is not an option here, sin	ice the question functions as	a filter]
[If dej	finition 'industry association']		
Q.11	Does your association <u>mainly</u> represent rese [One response only]	earch-based companies ("c	originators") or generic companies?
	Originators Generic companies	[NO RESPONSE]	[All answers> Go to Q.26]
[If dej	finition 'professional association']		
Q.12	Does your association <u>mainly</u> represent men [One response only]	mbers of a particular indu	stry, legal sector or academia?
	Particular industry Legal sector Academia		
	[Small text box] Other (please specify):		
		[NO RESPONSE]	[All answers> Go to Q.26]
[If dej	finition 'law firm']		
Q.13	What type of law firm do you represent? [One response only]		
	Global/international Regional (active in more than one country) National (office(s) in only one country) Local		
		[NO RESPONSE]	[All answers> Go to Q.14]

[If definition 'law firm']

Q.14 Does your law firm <u>mainly</u> represent research-based companies ("originators") or generic companies? [One response only]

Originators

Generic companies

Impossible to say, it varies

[NO RESPONSE]

[ All answers --> Go to Q.15]

[If definition 'law firm']

Q.15 Does your law firm <u>mainly</u> represent right holders or competitors of right holders? [One response only]

Right holders Competitors of right holders Impossible to say, it varies

[NO RESPONSE]

[ All answers --> Go to Q.26]

[If definition 'university/research']

Q.16 In which country is the university or research institution you represent located? Please select the country from the drop-down menu.

[One response only]

[Drop-down list of European countries, in alphabetical order]

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Luxembourg

Malta

The Netherlands

Poland

Portugal

Romania

Slovakia

Slovenia

Spain

Sweden

United Kingdom

[Small text box]

Other country (please specify): .....

[NO RESPONSE]

[All answers --> Go to Q.17]

[If definition 'university/research']

Q.17 Is the university or the research institution you represent involved in research and development activities in fields for which Supplementary Protection Certificate (SPC) protection is available? [One response only]

Yes [ --> Go to Q.18]

No [ --> Go to Q.40] [= definition 'university/research institution not involved in any SPC field']

["No response" is not an option here, since the question functions as a filter]

[If definition 'company' OR 'university/research']

Q.18 In the last ten years, has your company or university/research institution applied for authorisation to place a product on the European market before the European Medicines Agency (EMA) or the corresponding national authorities of any EU Member States?

If you are not sure about the exact number, a rough estimate will suffice.

[One response only]

[Small text box]

Yes, please enter the number of applications submitted during the last ten years:

No, not during the last ten years Don't know

[NO RESPONSE]

[All answers --> Go to Q.19]

[If definition 'company' OR 'university/research']

Q.19 In the last ten years, has your company or university/research institution applied for an SPC in Europe? [One response only]

Yes, several times [definition 'Yes, already dealt with SPCs'] [--> Go to Q.20]
Yes, only once [definition 'Yes, already dealt with SPCs'] [--> Go to Q.20]
No, never [--> Go to Q.25]
Don't know [--> Go to Q.25]

["No response" is not an option here, since the question functions as a filter]

[If definition 'company' OR 'university/research']

Q.20 Did your company or university/research institution ever obtain such an SPC? [One response only]

Yes

No

Don't know

[NO RESPONSE]

[All answers --> Go to Q.21]

[If definition 'company' OR 'university/research']

Q.21 On average, in how many EU Member States do you apply for SPCs? If you're not sure about the exact number, a rough estimate will suffice.

[One response only]
[Small text box]

Please enter number of EU Member States \_\_\_\_\_ Impossible to say, it varies

[NO RESPONSE]

[All answers --> Go to Q.22]

[If definition 'company' OR 'university/research']

Q.22 Is the geographical coverage of your SPC applications generally the same as the geographical coverage of the basic patent or is it smaller? [One response only]

The same Smaller than the basic patent Impossible to say, it varies

[NO RESPONSE]

[All answers --> Go to Q.23]

[If definition 'company' OR 'university/research']

Q.23 Now thinking specifically about cases where your company or university/research institution applies for an SPC and markets pharmaceutical products:

Does the geographical scope of the requested SPC generally match the geographical scope of the territory in which you market the pharmaceutical products? [One response only]

Always In most cases Rarely Never Impossible to say, it varies

[NO RESPONSE]

[All answers --> Go to Q.24]

[If definition 'company' OR 'university/research']

Q.24 How do SPCs and patents relate to your research activity? For each activity listed below, please select the applicable frequency.

[Allow only one response per line; a response must be entered for each line]

We conduct freedom to operate searches on granted patents or patent applications in the preparation stage of research projects.

Always	In most cases	Now and then	Never	Don't know
1 iiway 5	III IIIoot cases	110W and then	110101	Bon t know

We conduct freedom to operate searches on granted SPCs or SPC applications in the preparation stage of research projects.

Always In most cases Now and then Never Don't know
--

We consult patent applications or patents as a source of information for our research before we start or when we are completing a research project.

Always In most cases	Now and then	Never	Don't know
----------------------	--------------	-------	------------

[All answers --> Go to Q.25]

[If definition 'company' OR 'university/research']

Q.25 Which of the following statements apply if your research objectives involve testing whether molecules or biological substances fulfill specific intended purposes? [Multiple responses possible]

We manufacture the molecules or compounds that we need for our research activity ourselves We employ specific suppliers who manufacture the molecules or compounds or isolate the biological material We buy the compounds on the market without specifically employing a manufacturer.

[NO RESPONSE]

[All answers --> Go to Q.26]

[To all respondents:]

Q.26 a)Please indicate the extent to which you agree or disagree with each of the following statements:

[Allow only one response per line; a response must be entered for each line]

[Rotate all items at random]

The current SPC Regulations on medicinal and plant protection products (Regulation  $469/2009/EC^1$  and Regulation  $1610/96/EC^2$ ) effectively prevent research centres situated in EU Member States from relocating to countries outside the EU

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

The SPC system as currently practised encourages European manufacturers of generic medicines to relocate production facilities to countries outside the EU

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

The current SPC regime takes all the involved interests sufficiently into account

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

 $<sup>^1\</sup> http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg\_469\_2009/reg\_469\_2009\_en.pdf$ 

<sup>&</sup>lt;sup>2</sup> http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R1610:EN:HTML

The current SPC regime fosters the investment in research and development (R&D) activities

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

The current SPC Regulations act as an incentive to increase the time span between the pre-clinical trial phase and the filing of the marketing authorisation application

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

[ *All answers* --> *Go to Q.26 b)*]

26 b) Here are some additional statements. Again please indicate the extent to which you agree or disagree with each of them:

[Allow only one response per line; a response must be entered for each line]

[Rotate all items at random]

The current SPC Regulations act as an incentive to develop more products for which a longer time is needed until the marketing authorisation is obtained

Strongly	Agree	Disagree	Strongly	Impossible
agree		_	disagree	to say

The current SPC Regulations work well in most cases and do not result in legal uncertainty

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

The SPC Regulations, as interpreted by the CJEU, encourage investment in the development of combination products in Europe

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

The SPC Regulations, as interpreted by the CJEU, sufficiently protect new medical uses of known compounds (second medical use)

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

When it comes to examining SPC applications, the practice and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted

Strongly	Agree	Disagree	Strongly	Impossible
agree		_	disagree	to say

[ All answers --> Go to Q.27]

[To a	ll respondents:]
Q.27	Regulation 1768/92/EC (now Regulation 469/2009/EC) was conceived with traditional chemical compounds in mind. In the meantime, biopharmaceuticals and products of recombinant DNA technology (such as proteins antibodies, microbes, cells and cell lines, vaccines, viruses, DNA/RNA sequences or products for gene therapy) have grown in importance.
	In your opinion, does the present system adequately accommodate this technical development?
	Yes [> Go to Q.31] No [> Go to Q.28] No opinion [> Go to Q.31]
[Box]	for additional comments]
	Additional comments:
	["No response" is not an option here, since the question functions as a filter]
	Il respondents:]  Please explain why you think the present system does not adequately accommodate biopharmaceuticals and products of recombinant DNA technology.
[Larg	e text box]
	I have no opinion on that [NO RESPONSE] [ All answers> Go to Q.29]
[To al	ll respondents:]
	In your opinion, does Regulation 469/2009/EC need to be changed or amended in order to better accommodate biopharmaceuticals and products of recombinant DNA technology?)

Yes No

No opinion

[ --> Go to Q.30] [ --> Go to Q.31] [ --> Go to Q.31]

["No response" is not an option here, since the question functions as a filter]

[To all respondents:]
Q.30 In your opinion, what specific changes or amendments are needed with respect to Regulation $469/2009/EC$ and/or Regulation $1610/96$ in order to better accommodate these technical developments?
[Large text box]
I have no opinion on that
[NO RESPONSE] [ All answers> Go to Q.31]
[To all respondents:]
Q.31 Do you think that the current SPC Regulations have encouraged "evergreening" strategies?
Yes, to a great extent $[> Go \ to \ Q.32]$ Yes, somewhat $[> Go \ to \ Q.32]$ No, not substantially $[> Go \ to \ Q.33]$ Impossible to say, no opinion $[> Go \ to \ Q.33]$
[Box for additional comments]
Additional comments:
["No response" is not an option here, since the question functions as a filter]
[To all respondents:]
Q.32 In your view, what specific aspects of the SPC Regulations have encouraged "evergreening" strategies? Plea explain.
[Large text box]
I have no opinion on that
[NO RESPONSE] [ All answers> Go to Q.33]

[To all respondents:]

- Q.33 In your opinion, which of the following development activities should be covered by SPCs? [Multiple responses possible]
  - (1) The development of <u>new active ingredients</u>
  - (2) The development of <u>new formulations</u> of existing active ingredients
  - (3) The development of <u>new indications</u> for existing active ingredients
  - (4) The development of <u>new derivatives</u> of existing active ingredients

[Items 1 to 4 are to be rotated]

[Box for additional comments]

Additional comments:	
	•••••

[NO RESPONSE]

[ All answers --> Go to Q.34]

[To all respondents:]

Q.34 Please indicate the extent to which you agree or disagree with the following statement:

The development of new chemical entities requires more effort and investment and thus deserves longer legal protection ...

[One response only]

... compared to the development of new forms of existing active ingredients.

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

...compared to the development of new formulations of existing active ingredients.

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

... compared to the development of new indications for existing active ingredients.

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

[NO RESPONSE]

[ All answers --> Go to Q.35]

[To all respondents:]

Q.35 It is sometimes said that there is insufficient investment in the development of new antibiotics.

Would you favour or oppose changing Regulation 469/2009/EC in response to this assumed deficit? [One response only]

Favour  $[--> Go \ to \ Q.36]$  Oppose  $[--> Go \ to \ Q.37]$  Impossible to say, no opinion  $[--> Go \ to \ Q.37]$ 

["No response" is not an option here, since the question functions as a filter]

	[l respondents:]
Q.36	What changes would <u>you</u> propose in response to insufficient investment in the development of new antibiotics? [Large text box]
	Don't know [NO RESPONSE] [ All answers> Go to Q.37]
[To al	ll respondents:]
Q.37	It is sometimes said that there is insufficient investment in the development of some categories of orphan drugs.
	Would you favour or oppose changing Regulation 469/2009/EC in response to this deficit? [One response only]
	Favour $[> Go \ to \ Q.38]$ Oppose $[> Go \ to \ Q.39]$ Impossible to say, no opinion $[> Go \ to \ Q.39]$
	["No response" is not an option here, since the question functions as a filter]
[To al	ll respondents:]
Q.38	What changes would <u>you</u> propose in response to insufficient investment in the development of some categories of orphan drugs?
	[Large text box]
	Don't know
	[NO RESPONSE] [ All answers> Go to Q.39]

[To ali	ll respondents:]					
Q.39	Regulation $469/2009/EC$ was conceived in view of new molecules, new applications and new manufacturing methods. The pharmaceutical industry is now increasingly investing in new formulations of existing drugs, new delivery systems and combination products.					
	Taking this into account, would you favour or oppose amending the Regulation in this regard? [One response only]					
	Favour Oppose Impossible to say, no opinion					
	[NO RESPONSE] [All answers> Go to Q.40]					
[To al	ll respondents:]					
Q.40	Would you favour or oppose extending SPC protection to other fields of technology, such as medical devices cosmetic products, or food products and food additives (both for humans and animals)? [One response only]					
	Favour					
	["No response" is not an option here, since the question functions as a filter]					
[To al	ll respondents:]					
Q.41	To which types of products would you favour extending the current SPC protection? [Multiple responses possible]					
	Medical devices Cosmetic products Food additives Food products Other (please specify):					
	[NO RESPONSE] [ All answers> Go to Q.42]					
ITo al	ll respondents:]					
	Please comment on the pros and cons of extending SPC protection to other fields of technology, such as medica devices, cosmetic products, or food products and food additives (both for humans and animals)?					
	[Large text box]					
	<b>!</b>					

Don't know

[NO RESPONSE]

[ All answers --> Go to Q.43]

If definition is 'company' AND definition 'company not active in any SPC field' (Q.3) => Go to statistics

If definition is 'university/research' AND definition 'university/research institution not involved in any SPC field' (Q.17) => Go to statistics

[To all respondents:]

Q.43 Regulation 469/2009/EC does not define the concept of "active ingredient". All in all, would you favour or oppose including a definition of "active ingredient" in Regulation 469/2009/EC? [One response only]

Favour Oppose Undecided, no opinion

[Box for additional comments]

Additional comments:	

[NO RESPONSE]

[ All answers --> Go to Q.44]

[To all respondents:]

Q.44 Please read through the following proposed definition on the left side of the screen.

Proposed definition

"An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/83/EC and Directive 2001/82/EC to which the SPC application refers."

[Display the definition with a frame on the left side of the screen up to Q.44]

[Display the following question beside the definition]

In your view, would this definition of active ingredients provide legal certainty? [One response only]

Yes No Impossible to say

[NO RESPONSE]

[ All answers --> Go to Q.45]

[To all respo	ondents:]
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Q.45 Regulation 1610/96/EC<sup>3</sup> clarifies that "the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them". Neither Regulation 1610/96/EC nor Regulation 469/2009/EC do clarify, however, under which conditions the derivative may be considered a new product that satisfies the requirement under Art. 3 of Regulation 1610/96/EC.<sup>4</sup>

[Display the clarification with a frame on the left side of the screen]

Additional comments: .....

Proposed clarification

"The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless they differ significantly in properties with regard to safety and/or efficacy", see Art. 10(2)(b) Directive 2001/83/EC<sup>5</sup>

[Display the following question beside the clarification]

All in all, would you favour or oppose this clarification? [One response only]

Favour Oppose Undecided, no opinion

[Box for additional comments]

				1]	NO RESI	PONSE]	[ All answers> Go to Q.46]
[To al	ll respondents:]						
Q.46	1610/96/EĈ: According to the C Regulations when it 322/10 - Medeva <sup>6</sup> )	CJEU, a pit is specified what extension	roduct i ed in the t does th	s protec e wordi	cted by ng of th	the bas e claims	. 3(a) and (b) of Regulation 469/2009/EC and sic patent within the meaning of Art. 3(a) SPC of the basic patent (see, for instance, decision Cear criterion for deciding on SPC applications
	[Allow only one check						
	Clear criterion	0	0	0	0	0	Unclear criterion

["No response" is not an option here, since the question functions as a filter]

<sup>&</sup>lt;sup>3</sup> [Display link to Regulation 1610/96/EC: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R1610:EN:HTML

<sup>&</sup>lt;sup>4</sup> [Display article 3 of the regulation via mouse click]

<sup>&</sup>lt;sup>5</sup> Display article 10(2)(b) Directive 2001/83/EC

<sup>&</sup>lt;sup>6</sup>[Display link to C-322/10 CJEU decision:

http://curia.europa.eu/juris/celex.jsf?celex=62010CJ0322&lang1=en&type=TXT&ancre=]

[If in Q.46 the button on the far right side or the button next to that were selected]

Q.47 Please indicate the extent to which you agree or disagree with the following statement:

"According to the case law of the CJEU, the fact that the product falls within the scope of protection of one patent claim of the basic patent within the meaning of Art. 69 EPC (or any domestic provision corresponding to Art. 69 EPC)<sup>7</sup> is a necessary but not sufficient requirement to consider a product as protected by the basic patent within the meaning of Art. 3(a) SPC Regulations."

[One response only]

Strongly	Agree	Disagree	Strongly	Impossible
agree			disagree	to say

[ All answers --> Go to Q.48]

[To all respondents:]

- Q.48 When it comes to Art. 3 (a) of Regulation 469/2009/EC and Art. 3(a) of Regulation 1610/96/EC, which of the following amendments would you favour in order to ensure greater legal certainty? [One response only]
  - (1) A new paragraph in the Regulations with the following wording: "The product is protected by a basic patent in force when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC and corresponding national provisions and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed."

    According to this, the SPC may only be granted for subject matter to which the basic patent may be limited without violating Art. 123(2) EPC<sup>8</sup> or the corresponding national provisions
  - (2) A new paragraph with the following wording: "The product is protected when it falls under the scope of protection of the basic patent pursuant to Art. 69 EPC or the corresponding national provisions." This would be an infringement test.
  - (3) A new paragraph providing a "core inventive advance test" (as in UK case law) whereby the subject matter of the SPC is protected by the basic patent when two requirements are cumulatively met:
    - it falls under the scope of protection of the patent and
    - it represents the core inventive advance of the invention
  - (4) No amendment of Art. 3 (a) SPC Regulation is needed
  - (5) No opinion, impossible to say

[Rotate Items 1 to 3]

<sup>&</sup>lt;sup>7</sup>[Display link to article 69 of the EPC via mouse click: https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar69.html]

<sup>&</sup>lt;sup>8</sup>[Display link to article 123(2) of the EPC via mouse click: http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar123.html]

<sup>&</sup>lt;sup>9</sup> [Display link to Art. 69 EPC:

[Box f	for additional comments]	
	Additional comments:	
	[NO RESPONSE]	[ All answers> Go to Q.49]
[If def	inition 'law firm' or 'company']	
Q.49	Our next questions refer to variations of marketing authorisation	ns as described in Regulation $1234/2008/EC^{10}$ .
	In your view, should all variations of a marketing authorisation purposes of Art. 3(b) and (d) Regulation 469/2009/EC <sup>11</sup> or not? [One response only]	constitute a <u>new</u> marketing authorisation for the
	Yes No No opinion	
[Box f	for additional comments]	
	Additional comments:	
	[NO RESPONSE]	[ All answers> Go to Q.50]
[If def	inition 'law firm' or 'company']	
	In your opinion, should changes that require an extension of the new marketing authorisation for the purposes of Art. 3(b) and ([One response only]]	
	Yes No No opinion	
[Box f	for additional comments]	
	Additional comments:	
	[NO RESPONSE]	[ All answers> Go to Q.51]

10 [Display link to Regulation 1234/2008/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF]
11 [Display link to article 3(b) of Regulation 469/2009 via mouse click]
12 [Display link to article 3(b) of Regulation 469/2009 via mouse click]

[If definition	'law firm'	or	'company']
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Q.51 Regulation 1234/2008/EC<sup>13</sup> refers to three types of variations which have different implications depending on the likely impact of the change on the quality, safety or efficacy of the medicinal product. This includes "type II variations", that is, major variations that do not constitute an extension and which may have a significant impact "on the quality, safety or efficacy" of the medicinal product concerned.

In your view, should any "type II variation" constitute a new marketing authorisation for the purposes of Art.  $3(b)^{14}$  and  $(d)^{15}$  Regulation 469/2009/EC or not? [One response only]

Yes

No

No opinion

[Box for additional comments]

Additional comments:	

[NO RESPONSE]

[ All answers --> Go to Q.52]

[If definition 'law firm']

Q.52 In the decision 'Neurim C-130/11', <sup>16</sup> the CJEU set out the conditions under which a "different application of the same product" meets the requirements for SPC eligibility.

Do you agree with this case law? [One response only]

Yes

No

No opinion

[Box for additional comments]

Additional comments:	

[NO RESPONSE]

[ All answers --> Go to Q.53]

<sup>&</sup>lt;sup>13</sup> [Display link to Regulation 1234/2008/EC:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF]

<sup>&</sup>lt;sup>14</sup> [Display link to article 3(b) of Regulation 469/2009 via mouse click]

<sup>&</sup>lt;sup>15</sup> [Display link to article 3(d) of Regulation 469/2009 via mouse click]

<sup>&</sup>lt;sup>16</sup> [Display the link to decision 'C-130/1 Neurim 1': http://curia.europa.eu/juris/document/document.jsf?text=&docid=125216&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=237129]

[If definition 'law firm']

Q.53 Would you consider a type II marketing authorisation variation (Art. 2 para 3 of Regulation 1234/2008)<sup>17</sup> as sufficient to meet the requirements for a "different application of the same product", as set out in the Neurim decision ('Neurim C-130/11')<sup>18</sup>?

[One response only]

Yes, sufficient No, not sufficient No opinion

[NO RESPONSE]

[ All answers --> Go to Q.54]

[If definition 'law firm' OR 'company']

Q.54 Our next question is about the possibility—by filing an SPC application—of referring to a third-party marketing authorisation without obtaining the consent of that third party.

In your experience, to what extent does that lead to practical problems for the holder of the authorisation in obtaining a license from the patent holder?

[One response only]

To a great extent
To a moderate extent
To a lesser extent
Rarely/not at all
Don't know, no opinion

[NO RESPONSE]

[ All answers --> Go to Q.55]

[If definition 'law firm' OR 'company']

- Q.55 The case law of the CJEU is currently not clear with respect to third-party marketing authorisations: Which of the following clarifications would you prefer?

  [One response only]
  - (1) The applicant can refer to a third-party marketing authorisation whether the holder of the marketing authorisation agrees to it or not and with no formalities.
  - (2) The applicant may only refer to a third-party marketing authorisation when the third party is in agreement and evidence of his/her consent is included in the application.
  - (3) No opinion

[Box for additional comments]

Additional comments:	

[NO RESPONSE]

[ All answers --> Go to Q.56]

<sup>&</sup>lt;sup>17</sup> [Display the link to Art. 2 para 3 of Regulation 1234/2008: http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg\_2008\_1234/reg\_2008\_1234\_en.pdf

<sup>&</sup>lt;sup>18</sup> [Display the link to decision 'C-130/1 Neurim 1': http://curia.europa.eu/juris/document/document.jsf?text=&docid=125216&pageIndex=0&doclang=EN&mode=lst&dir=&oc c=first&part=1&cid=237129]

[If definition 'law firm' OR 'company' OR 'professional association']

No opinion

56.	In Europe it is not possible to obtain an SPC if the patent expires before the marketing authorisation has beer granted. By contrast, in the United States it is possible to obtain a patent extension even if the patent expires before the marketing authorisation has been granted. The patent holder can in fact file an application for ar interim extension before the expiration date of the patent.
	In practice, do you favour amending the EU Regulations in this regard?
	Yes No
	[Box for additional comments]
	Additional comments:
	No opinion [NO RESPONSE] [ All answers> Go to Q.57]
[If de	efinition 'law firm' OR 'company' OR 'professional association']
	Similari ma firm Oil company Oil projectional accomment
57.	In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself.
57.	In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the
57.	In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself.
57.	In Europe, the prevailing view is that it is not possible to obtain an SPC if the patent was granted after the expiration date of the patent itself.  In practice, do you favour amending the EU Regulations in this regard?  Yes

[NO RESPONSE]

[ All answers --> Go to Q.58]

[If definition 'law firm' OR 'company']

Q.58 Patent claims are statements that define the matter for which protection is sought in terms of the technical features of the invention. So far, Regulation 469/2009/EC<sup>19</sup> does not seem to provide that such statements should be included in the SPC application. If the subject matter for which protection is sought had to be specified already in the SPC application in a form similar to patent claims:

Do you think that this would facilitate the examination procedure or, on the contrary, make it more difficult, or do you think it would make no difference?

[One response only]

Facilitate Make it more difficult Would make no difference No opinion

[NO RESPONSE]

[ All answers --> Go to Q.59]

[If definition 'law firm' OR 'company']

Q.59 Which of the following measures would you expect to have a positive impact? Please mark all applicable measures.

[Multiple responses possible]

If the procedures for granting SPCs were harmonised within the EU

If third parties had the right to file observations like in proceedings before the EPO under Art. 115 EPC<sup>20</sup>

If the examination of all requirements provided under Art. 3 of the SPC Regulations<sup>21</sup> was made mandatory

If oppositions against SPCs were made possible in cases where the right was granted in violation of Art. 3 of the Regulations

I do not expect any of the above to have a positive impact

[NO RESPONSE]

[ All answers --> Go to Q.60]

[If definition 'law firm' OR 'company']

Q.60 There are suggestions for new rules in both SPC Regulations (Regulation 469/2009/EC and Regulation 1610/96/EC) analogous to some EPC rules. Which of the following rules would you welcome under SPC Regulations?

First, would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC<sup>22</sup>?

[One response only]

Yes

No

No opinion

[NO RESPONSE]

[ All answers --> Go to Q.61]

<sup>&</sup>lt;sup>19</sup> [Display the link to Regulation 469/2009:

http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg\_469\_2009/reg\_469\_2009\_en.pdf]

<sup>&</sup>lt;sup>20</sup> [Display the link to Art. 115 EPC:

https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar115.html]

<sup>&</sup>lt;sup>21</sup> [Display the link to article 3 of Regulation 469/2009 via mouse click]

<sup>&</sup>lt;sup>22</sup> [Display the link to Art. 105a EPC22: https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar105a.html]

[If def	finition 'law firm' OR 'company']				
Q.61	Secondly, would you welcome a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138 (3) EPC <sup>23</sup> ? [One response only]				
	Yes No No opinion				
		[NO RESPONSE]	[ All answers> Go to Q.62]		
[If de	efinition 'law firm' OR (definition 'compa	ny' AND 'Yes, already dealt with	h SPCs' according to Q.19)]		
Q.62	In your experience as an SPC application burden for applicants, and where has		national granting procedures that constite?	ute a	
	[Large text box]				
	Don't know				
		[NO RESPONSE]	[ All answers> Go to Q.63]		
[If def	finition 'company']				
Q.63	Does the availability of SPC protect produce active ingredients? [One response only]	ction affect your company's o	decisions about where, in which countr	ry, to	
	Yes No Varies from case to case No opinion				
		[NO RESPONSE]	[ All answers> Go to Q.64]		
[If def	finition 'company']				
Q.64	Is the scope of the Bolar exemption where to conduct pre-clinical and clin [One response only]		intry a relevant factor for you when dec	iding	
	Yes No Varies from case to case No opinion				
		[NO RESPONSE]	[ All answers> Go to Q.65]		

<sup>&</sup>lt;sup>23</sup> [Display the link to Art. 138 (3) EPC: https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar138.html]

To all	respondents:]
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Q.65 Are you in favour of a narrow Bolar exemption as laid down in Art. 10(6) Directive 2001/83/EC<sup>24</sup> and Art. 13(6) Directive 2001/82/EC<sup>25</sup> and, by reference, in Art. 27(d) UPCA<sup>26</sup>; or would you favour a broader exemption as recently introduced in UK patent law<sup>27</sup>? [One response only]

Narrow Bolar exemption Broader Bolar exemption No opinion

[NO RESPONSE]

[ All answers --> Go to Q.66]

[To all respondents:]

Q.66 SPC protection is not provided in all WTO Member States. Moreover, countries with a significant generic industry exclude new uses of known compounds from patent protection and strongly limit the patentability of new forms of existing active ingredients. Consequently, the production of a substance for a specific technical or therapeutic purpose in these countries is or becomes patent-free, while a patent or an SPC in Europe may still exist.

In such an asymmetric situation, to what extent would you expect generic manufacturers to outsource the production of active ingredients that are still protected in Europe, but that are patent-free in several non-European jurisdictions?

[One response only]

Always In most cases Occasionally Never No opinion, impossible to say

[NO RESPONSE]

[ All answers --> Go to Q.67]

[To all respondents:]

Q.67 The introduction of a "SPC manufacturing waiver" for the export of SPC-protected active ingredients to patent-free markets is currently being considered. This would allow generic companies to manufacture SPC-protected drugs in Europe for export to patent-free countries without infringing the SPC rights. By manufacturing we understand "manufacturing of a final product", and not packaging.

What do you think of the idea of introducing such an "SPC waiver"?

No opinion

[Large text box]

[NO RESPONSE]

[ All answers --> Go to Q.68]

<sup>&</sup>lt;sup>24</sup> [Display the link to Art. 10(6) Directive 2001/83/EC: http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/dir\_2001\_83\_consol\_2012/dir\_2001\_83\_cons\_2012\_en.pdf]

<sup>&</sup>lt;sup>25</sup>[Display the link to Art. 13(6) Directive 2001/82/EC http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-5/dir\_2001\_82\_cons2009/dir\_2001\_82\_cons2009\_en.pdf]

<sup>&</sup>lt;sup>26</sup> [Display the link to Art. 27(d) UPCA https://www.unified-patent-court.org/sites/default/files/upc-agreement.pdf]

<sup>&</sup>lt;sup>27</sup> [Display the link to http://www.legislation.gov.uk/uksi/2014/1997/made]

[To all respondents:]

Q.68 Assuming a manufacturing waiver was introduced, which of the following measures would you suggest in order to prevent stockpiling or exportation to countries where equivalent protection is still in force? Please mark the applicable measures:

[Multiple responses possible]

- Granting the patent holder a right to information, enforceable before the courts
- Making it mandatory for the manufacturer to provide specific labelling for the product
- Making it mandatory for the manufacturer to communicate to the right holder the quantity produced and the destination before starting distribution
- New rules shifting the burden of proof for infringement from the SPC holder to the manufacturer
- Other (please specify).... [Small text box]
- I do not suggest any such measures

[Box for additional comments]

Additional comments:

No opinion

[NO RESPONSE]

[ All answers --> Go to Q.69]

[To all respondents:]

Q.69 The creation of a "unitary SPC" which can be obtained with a single granting procedure is currently under consideration. In your opinion, is there actually a need for creating a "unitary SPC" or is there no actual need? [One response only]

Yes, there is actually a need [ --> Go to Q.70] No, there is no need for that [ --> Go to Q.76] No opinion [ --> Go to Q.76]

["No response" is not an option here, since the question functions as a filter]

[To all respondents:]

- Q.70 And in your opinion, which authority shown on this list should grant a "unitary SPC"? [One response only]
  - National patent offices based on a mutual recognition system [definition 'mutual recognition system'] [ --> Go to Q.71]
  - An EU authority such as the EU Intellectual Property Office (EUIPO) [definition 'EUIPO, EMA, EPO, new EU office'] [ --> Go to Q.72]
  - An EU authority such as the European Medicines Agency (EMA) [definition 'EUIPO, EMA, EPO, new EU office'] [ --> Go to Q.72]
  - The EPO [definition 'EUIPO, EMA, EPO, virtual EU office'] [ --> Go to Q.72]
  - A virtual patent office created based on new EU rules and composed of examiners from national patent offices [definition 'EUIPO, EMA, EPO, virtual EU office'] [ --> Go to Q.72]

[Box for additional comments]

Additional comments:

["No response" is not an option here, since the question functions as a filter]

[If definition 'mutual recognition system', as per Q.70]

Q.71 You opted for a mutual recognition system. In that case, in which language should the "unitary SPC" be filed and prosecuted?

[One response only]

In English In the language of the respective national office No preference Don't know, no opinion

[NO RESPONSE]

[ All answers --> Go to Q.73]

[If definition 'EUIPO, EMA, EPO, virtual EU office', as per Q.70]

Q.72 You opted for an EU authority/the EPO/a virtual EU patent office. In that case, in which language should the "unitary SPC" be prosecuted?

[One response only]

- In English only
- EPO solution (English, French, and German)
- In the same five working languages of the EUIPO
- In the official language of any participating Member State, accompanied by a translation into English
- Don't know, no opinion

[The first four items are to be rotated randomly]

[NO RESPONSE]

[ All answers --> Go to Q.73]

[To all respondents:]

Q.73 In which language should the "unitary SPC" be granted and, possibly, translated? [One response only]

If a national office is the granting authority, in the language of the granting office plus English In all languages of the countries for which the "unitary SPC" is valid Two-language solution, as with the EUIPO

Three-language solution, as with the EPO

[NO RESPONSE]

[ All answers --> Go to Q.74]

Q.74	In your view, should the decisions of th Patent Court (UPC) or before an EU court or designs?  [One response only]	e body that grants a "unitar art, such as the Court of Firs	ry SPC" be subject to appeal before the Ust Instance, as in the case with EU trade	Jnified marks
	Before the UPC Before an EU court No preference No opinion			
		[NO RESPONSE]	[ All answers> Go to Q.75]	
[To al	l respondents:]			
Q.75	Should a "unitary SPC" be granted onl granted by EMA? [One response only]	ly when the product is cov	vered by a European marketing author	isation
	Yes No No opinion	[NO RESPONSE]	[ All answers> Go to Q.76]	
		[NO RESI ONSE]	[ 1111 unswers> Go to Q.70]	
[To al	l respondents:]			
Q.76	Do you have any further comments, que on other aspects regarding SPCs that ha			
	[Large text box]			
				·•
		[NO RESPONSE]	[ All answers> Go to Q.77]	
[To al	l respondents:]			
	If there is anything else you would like please feel free to do so now:	to suggest or tell us in conn	ection with this survey,	
	[Large text box]			
				••
		[NO RESPONSE]	[ All answers> Go to S1]	

[To all respondents:]

### STATISTICS: In conclusion, we would like to ask you to provide some information about yourself and your company/university/research institution/association/law firm for statistical purposes.

[To all respondents:]

S1. What is your age? (Please check the applicable category) [One response only]

Under 30

30 - 39

40 - 49

50 - 59

60 and over

[NO RESPONSE]

[All answers --> Go to S2]

[If definition 'company']

S2. What position do you hold at your company? [One response only]

Owner

Member of the board of directors

Director

Executive, managerial position

Employee in non-managerial position

OTHER, please specify:....

[NO RESPONSE]

[All answers --> Go to S4]

[If definition 'law firm']

S3. What position do you hold at your office/firm? [One response only]

Partner

Employed as lawyer/patent attorney

Other law firm employee

[NO RESPONSE]

[All answers --> Go to S12]

[If definition 'company']

S4. What is the total number of employees at your company? If you work for a company with offices, plants or facilities in more than one location, please indicate the total number of <u>all</u> employees. [One response only]

Less than 100 100 – 499 500 – 999 1,000 – 9,999 10,000 or more

[NO RESPONSE]

[All answers --> Go to S5]

[If definition 'company']

S5. Approximately how high was the total turnover of your company in the year 2015 in euros? Again, if you work for a company with offices, plants or facilities in more than one location, please indicate the total turnover of <u>all</u> locations on a worldwide basis. [One response only]

Less than 10 million euros 10 to less than 100 million euros 100 to less than 500 million euros 500 to less than 1 billion euros 1 billion to less than 10 billion euros 10 billion euros or more

[NO RESPONSE]

[All answers --> Go to S6]

[If definition 'company']

> In 1 EU Member State In 2 – 4 EU Member States In 5 – 9 EU Member States In 10 – 28 EU Member States

> > [NO RESPONSE]

[*All answers --> Go to S7*]

[If definition 'company']

S7. For each of the activities listed below, please select the applicable share that your company completes in the EU.)

[Allow only one response per line; a response must be entered for each line]

Research & development	All/almost all	A fairly large share	A fairly small share	None/almost none
Manufacturing	All/almost all	A fairly large share	A fairly small share	None/almost none
Distribution, marketing	All/almost all	A fairly large share	A fairly small share	None/almost none

[NO RESPONSE]

[All answers --> Go to S8]

[ --> Go to S12] [ --> Go to S9]

[ --> Go to S12]

[If definition 'company']

S8. Is your company a parent company, a subsidiary or an independent company?

Parent company Subsidiary Independent

["No response" is not an option here, since the question functions as a filter]

[If definition 'company']

S9. Is your parent company registered outside the European Union?

Yes No

[NO RESPONSE] [ --> Go to S12]

[If definition 'association']

S10. What position do you hold at the association you represent?

Please specify:

[Small text box]



[NO RESPONSE]

[All answers --> Go to S12]

[If de	finition 'university/research']	
	, v	ian way rankasant?
511.	What position do you hold at the university or research instituti	ion you represent:
	Please specify:	
[Sma	[l text box]	
	[NO RESPONSE]	[All answers> Go to S12]
S12.	A summary of the main results of the survey will be publish accessible online in fall 2017. If you would like to be notified email address in the box below.  If you do not wish to be notified, please click the button to proceed the text box.	once the results are available, please enter your
	Email address:	[All answers> Go to end panel]
	ill respondents] in panel]	
	You have now reached the end of the	CHTYON

You have now reached the end of the survey. Thank you very much for participating. Your opinions are very important to us.

## Data Concerning the Accuracy of Representative Surveys (Statistical Tolerance Levels of the Findings)

Percentages of a population ascertained in representative surveys using sampling principles can deviate from the percentage which is actually present in that population within the framework of certain levels of tolerance.

The size of a particular margin of tolerance depends on the sampling procedure selected, the size of the sample, and the percentage of respondents who display the attribute of interest. For decades, researchers have debated the issue of whether tolerance levels can only be calculated for samples selected in accordance with the random principle ("random sampling") or whether they also apply to samples selected using the quota technique. This question cannot be resolved via theoretical arguments, but rather only by means of empirical values obtained in practice. Both the random and quota sampling techniques are susceptible to error when applied in concrete cases. Provided that they are applied correctly, all of the data obtained thus far indicate that the two selection methods are of equal merit and equally suitable as the basis for calculating tolerance levels for the percentages ascertained. For more information, see: E. Noelle-Neumann and T. Petersen, *Alle, nicht jeder. Einführung in die Methoden der Demoskopie*, 4th ed. (2005), Berlin: Springer, pp. 263-276.

The following table shows the <u>maximum</u> deviation in a representative sample of n persons between the percentage obtained (p) and the actual value, with a probability level of 95 percent.

Statistical Tolerance Levels (confide	ence probability: 95 percent)
---------------------------------------	-------------------------------

Number of persons in the sample n	p = percentage of respondents who display the attribute									
	50 50	45 55	40 60	35 65	30 70	25 75	20 80	15 85	10 90	5 95
100	9.80	9.75	9.60	9.35	8.98	8.49	7.84	7.00	5.88	-
150	8.00	7.96	7.84	7.63	7.33	6.93	6.40	5.71	4.80	3.49
200	6.93	6.89	6.79	6.61	6.35	6.00	5.54	4.95	4.16	3.02
300	5.66	5.63	5.54	5.40	5.19	4.90	4.53	4.04	3.39	2.47
400	4.90	4.88	4.80	4.67	4.49	4.24	3.92	3.50	2.94	2.14
500	4.38	4.36	4.29	4.18	4.02	3.80	3.51	3.13	2.63	1.91
600	4.00	3.98	3.92	3.82	3.67	3.46	3.20	2.86	2.40	1.74
700	3.70	3.69	3.63	3.53	3.39	3.21	2.96	2.65	2.22	1.61
800	3.46	3.45	3.39	3.31	3.18	3.00	2.77	2.47	2.08	1.51
900	3.27	3.25	3.20	3.12	2.99	2.83	2.61	2.33	1.96	1.42
1000	3.10	3.08	3.04	2.96	2.84	2.68	2.48	2.21	1.86	1.35
1100	2.95	2.94	2.90	2.82	2.71	2.56	2.36	2.11	1.77	1.29
1200	2.83	2.81	2.77	2.70	2.59	2.45	2.26	2.02	1.70	1.23
1300	2.72	2.70	2.66	2.59	2.49	2.35	2.17	1.94	1.63	1.18
1400	2.62	2.61	2.57	2.50	2.40	2.27	2.10	1.87	1.57	1.14
1500	2.53	2.52	2.48	2.41	2.32	2.19	2.02	1.81	1.52	1.10

Example of how to read the table: If it is found in a representative survey of the population with n = 1,500 persons that 80 percent of these persons are familiar with a particular product, the tolerance level can be determined by finding the point of intersection between the line n = 1,500 and the column p = 80, showing that this finding has a tolerance margin of +/- 2.02 percent. We can thus say with 95 percent probability that the actual value which would have been ascertained in a survey of the entire population would have been somewhere between 77.98 percent and 82.02 percent.

When using tolerance margin tables, it is important to remember that the values within the margins are not equally probable. Rather, the value actually obtained has the greatest probability, as illustrated by Gauss' bell curve.

*Note:* The reason for the gap in the upper right-hand corner of the table is that the standard error cannot be expressed by means of one single number in such cases. The table above is derived from an approximation of the binomial distribution, which is in line with the distribution of percentages in the sample, via the normal distribution. When the percentage of persons who display the attribute in question approaches 0 percent or 100 percent, the binomial distribution becomes noticeably unsymmetrical and deviates from the normal distribution, i.e. the margins of error in the + and - range take on different values.

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