

## **Summary Report**

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### **2019 – Study Question – Patents**

#### **Plausibility**

##### **Introduction**

This Study Question concerns the question whether “plausibility” should be considered as a (further) patentability requirement, and if so, how to define its preconditions.

Plausibility, if considered as a patentability requirement, generally addresses the question whether there is sufficient evidence/disclosure that the purported technical effect of a claimed invention can be actually achieved, as opposed to mere “speculative” patent applications. In this respect the plausibility requirement can relate to various established disclosure requirements, including sufficiency, clarity, utility, industrial applicability and use of post-filing data, as well as traditional patentability requirements such as novelty and inventive step.

This Study Question examines whether “plausibility” should be considered as a (further) patentability requirement, and if so, how to define its preconditions. Given the (potentially) extremely broad and sweeping implications of this requirement, the scope of this Study Question shall be limited to the sub-issues of (1) the general credibility of the invention, (2) the general prohibition of speculative filings and (3) specific restrictions regarding “prophetic” examples.

The aim is to analyze whether the plausibility requirement should include some or all of the above-mentioned sub-issues, and if so, which would be the “best fit” for plausibility within the established patentability requirements.

In studying plausibility specifically, this Study Question does not aim to revisit the general sufficiency of disclosure requirement, the general utility requirement or the use of post-filing data in support of patentability.

The Reporter General has received Reports from the following Groups and Independent Members in alphabetical order: Argentina, Austria, Belgium, Brazil, Bulgaria, Canada, China, Denmark, Ecuador, Estonia, Finland, France, Germany, Hungary, Italy, Japan, Mexico, the Netherlands, New Zealand, Norway, Paraguay, Philippines, Poland, Republic of Korea,

Russian Federation, Singapore, Spain, Sweden, Switzerland, Taiwan (Independent Members), Turkey, United Kingdom (UK), United States of America (U.S.), and Vietnam.

34 reports were received in total.<sup>1</sup> The Reporter General thanks the Groups and Independent Members for their helpful and informative reports. All reports may be accessed [here](#).

The Reports provide a comprehensive overview of national and regional laws and policies relating to plausibility set out in three parts:

- Part I – Current law and practice
- Part II – Policy considerations and proposals for improvements of the current state of the law
- Part III – Proposals for harmonisation.

This Summary Report does not summarise Part I of the Reports received. Part I of any Report is the definitive source for an accurate description of the current state of the law in the jurisdiction in question.

This Summary Report has been prepared on the basis of a detailed review of all Reports (including Part I) but focuses on Parts II and III, given AIPPI's objective of proposing improvements to, and promoting the harmonisation of, existing laws. As it is a summary, if any question arises as to the exact position of a particular Group in relation to Parts II or III, please refer to the relevant Report directly.

In this Summary Report:

- references to Reports of or responses by one or more "Groups" may include references to Independent Members;
- where percentages of responses are given, they are to the nearest 5%; and
- in Part IV below, some conclusions have been drawn in order to provide guidance to the Study Committee for this Question.

## **I. Current law and practice**

For the replies to Questions 1) - 14) set out in the Summary Guidelines for this Study Question, reference is made to the full Reports. The Study Guidelines may be accessed [here](#).

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<sup>1</sup> Reports received after 01 July 2019 are listed above but their content is not incorporated into this Summary Report.

## **II. Policy considerations and proposals for improvement of your current law**

### **15) Are there aspects of your Group's current law relating to plausibility that could be improved? If YES, please explain.**

20 of the responding 33 Groups (60 %) stated NO, generally referring to the fact the current national law does not foresee any specific plausibility provision, and that inclusion of an express plausibility requirement is not desirable.

The German Group (stating YES) notes a tendency in the case law of the European Patent Office to treat plausibility as a de-facto requirement in the sense that a patent application may be refused or a patent revoked; however, the German Group does not recognize a need for an additional patentability requirement beyond those already codified in the European Patent Convention and in German law.

### **16) Under your Group's current law, does the availability of patent protection aim to incentivize an early disclosure of technical achievements, or rather the disclosure of “completed” inventions (which may involve a mandatory disclosure of a “best mode”)?**

21 of the responding 33 Groups (65 %) stated that the current law aims to incentivize both an early disclosure of technical achievements, and the disclosure of “completed” inventions.

The Japanese Group observed these two parallel legislative aims are at odds with each other and that their current national practice reflects the policy that an invention needs to be nearly complete but does not need to be perfect.

7 Groups answered that their laws aim to incentivize the disclosure of “completed” inventions, partly involving a mandatory disclosure of a “best mode”. 5 Groups stated that their laws aim to incentivize an early disclosure.

### **17) Under your Group's current law, does the plausibility requirement, if any, interfere with the incentive for an early disclosure provided by the first-to-file system?**

22 of the responding 33 Groups (65 %) stated NO; frequently referring to the fact the current national law does not foresee any specific plausibility provision.

The Philippine Group (stating NO) explains that the presence of the plausibility requirement does not interfere with the incentive for an early disclosure since the “credibility requirement” and the prohibition against “speculative filings” and “prophetic examples” merely ensures that patents, in return for the exclusive rights granted by the State, will truly contribute to the diffusion of knowledge and information.

### III. Proposals for harmonisation

#### 18) **Do you consider that harmonization regarding plausibility is desirable?**

The clear majority, i.e. 27 of the responding 33 Groups (80 %) stated YES.

As the Danish Group explains, harmonization would allow applicant to make an overall estimation of the right timing for filing the patent application i.e. when adequate data has been obtained to fulfill the requirements of plausibility of inventive step. When the requirements differ in the various jurisdictions, the right time for filing is never there. In some jurisdictions early filing is possible – and possibly necessary to be the first to file. In other jurisdictions early filing results in a very narrow scope of protection since the application as filed did not contain enough data covering the entire plausible scope of protection.

The Polish Group adds that harmonization is particularly important in view of the disparities between the national and the EPO practice, creating a paradox situation that a patent for the same invention may be available in the EP path, but not before the national office.

#### 19) **Should there be a plausibility requirement?**

15 of the responding 32 Groups (45 %) stated YES, while 17 Groups (55 %) stated NO.

The Chinese Group (stating YES) views the plausibility requirement essentially as a protection of the industry in less technologically advanced countries. Absent a plausibility requirement, technologically advanced companies may obtain exclusive right for patents without sufficient experimental data through early basic research, restricting the development of less developed enterprises.

In contrast, The French Group (stating NO) is of the opinion that under the current system it is not necessary to provide an additional requirement of plausibility. This is especially the case if the legal requirements of patentability and validity are correctly applied, in particular according to the well-established principle that the scope of claims must be proportional to the technical contribution made to the state of the art.

The Mexican Group (stating NO) raises the concern that a plausibility requirement may have a negative impact on the notion and applicability of the other patentability requirements such as, novelty, inventive step, support and clarity. The Canadian Group (stating NO) seconds and adds that the introduction of a plausibility requirement would likely create legal uncertainty without a commensurate benefit.

#### 20) **Should plausibility be a “credibility” requirement that excludes patent applications describing a technical effect of the claimed invention which however looks “incredible”, e.g. because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?**

14 of the responding 31 Groups (45 %) stated YES, while 17 Groups (55 %) stated NO.

The Argentine Group (stating NO) points out that such requirement risks being applied subjectively, especially when applied to inventions in “cutting-edge” technological fields, where results can often be surprising or unexpected, possibly leading to a lack of credibility. This would put these inventions in a further disadvantage in comparison with well-established and mature technologies that are often the object of “incremental” inventions.

The Dutch Group (stating NO) raises the point that such requirement puts the standard too low. A described and/or claimed effect would already be plausible if it does not look “incredible”. This opens the door to speculative or wide-ranging unsubstantiated claims. Unless a claim is prima facie incredible, it would meet the requirement.

The Bulgarian Group (stating YES) points out that the “incredible” technical effect must be sufficiently explained and supported in order to obtain patent protection. Otherwise any absurd idea may be protected with the excuse that it shows “incredible” technical effect.

Independent Members (Taiwan, stating YES) specify that a surprising effect should not be excluded from patentability simply because it appears non-credible.

**a) If yes, which standard should apply to determine the credibility of the invention? Is the credibility determined from the perspective of a person having ordinary skills in the art, or from the perspective of an expert in the field?**

18 of the responding 19 Groups substantively answering this question agree that the credibility should be determined from the perspective of a person having ordinary skill in the art.

The Danish Group thinks that this requirement should result in a higher level of details provided in the patent description to support the (surprising) results, in that the person having ordinary skill in the art would not be motivated to do research of his own to establish whether the invention can be put into practice in some circumstances, not specifically described in the patent, when prevailing technical opinion suggests the outcome will be failure.

The Mexican Group thinks that the standard for assessing the credibility in the context of the question should be the same standard used for assessing enablement of the detailed description, whatever the standard is in every country. Particularly if one of the options needs to be chosen for standardization the standard of an expert in the field should prevail because the results may “look incredible” for those having ordinary skills in the art, and those things credible for those with ordinary skill should be credible for those experts in the field.

The Swedish Group states that different standards should be applied to determine credibility. A first standard should be applied when the technical effect is a claimed feature, i.e. for second medical use claims. For such inventions, credibility relates to insufficiency of disclosure rather than inventive step. The standard should be assessment of plausibility of the technical effect per se. A second standard should be applied when the technical effect is a non-claimed feature. For such inventions, credibility relates to inventive step rather than

insufficiency of disclosure. The standard should be assessment of plausibility of the technical effect per se but also by determining if the technical effect is implied by or at least related to the technical problem initially mentioned in the application as filed.

The Turkish Group is of the opinion that the requirement means the description needs to contain in vitro data and in vivo data, a comparison with general knowledge in the art, experimental data, sufficiently clear information how to carry out the invention, and even more detailed examples and evidence for the subject matter of the patent claims.

The UK Group thinks that the standard to be applied to determine the credibility of the invention should: (i) be a pre-condition to validity, (ii) represent a low threshold to overcome, (iii) be narrowly understood, and (iv) be relatively undemanding. Thus, the threshold should be met if, e.g., the specification provides an educated prediction based on a reasonably credible theory or a priori reasoning: (i) as to why the invention will work, or (ii) which enables the skilled person to test the invention (without undue burden). On the flip side, a mere theoretical or purely hypothetical assumption or bare assertion, without a theoretical or reasoned basis, should not be enough to satisfy the credibility threshold.

The US Group is of the opinion that the credibility requirement should be shaped in a way which avoids confusion with separate legal requirements, such as enablement, utility, written description, and definiteness. Credibility should be a low threshold. The question should not be whether the invention contradicts common perceptions, but whether the invention appears to defy the laws of physics or the laws of nature, such as to defy any reasonable perceived possibility that the invention could work as claimed, that it appears to be incredible to any reasonable skilled person. Examples may include a perpetual motion machine, or a drug to cure all cancers. Merely contradicting common perception in the field or having a surprising effect is not the standard to be applied.

**b) Should all the promises of the patent description have to seem achievable for the person skilled in the art?**

11 of the responding 29 Groups (40 %) stated YES, while 18 Groups (60 %) stated NO.

The US Group (stating NO) explains that the relevant analysis should be on the “claimed” invention. The question should be on whether the claimed invention appears incredible and not whether it is likely to achieve the various promises or statements in the specification. For a claimed invention to appear achievable to a person skilled in the art, the art would need to be predictable and then the question gets confused with obviousness if it is readily determined to be achievable. With regard to considering the “promises” in the patent description, the description may include additional descriptive matter beyond what is claimed, and therefore not relevant to determining the credibility of the “claimed” invention. Patent descriptions often do not describe inventions in terms of “promises.” Often, the description is written that one embodiment “may” do this, and another embodiment “may” do that. Such objectives are not promises. Moreover, to the

point that the operative word in the question is “all,” then it is proposed that if only at least one object of the claimed invention seems achievable, that is, not incredible, to the skilled person in the art, then the claimed invention should be considered credible. Moreover, even if the promises or objects of an invention depart from what is considered achievable to a person skilled in the art, they may still be considered credible. Some credible inventions by their nature depart from conventional wisdom, or the prior art teaches away from the invention such that it does not appear achievable. Some inventions may provide a surprising and/or unexpected result relative to the state of the art. These inventions may still be considered credible in that they do not depart from known laws of physics or laws of nature.

The UK Group (stating NO) agrees saying that only the technical contribution upon which the patentee relies as protected by the claims of the patent needs to be made plausible by the disclosure of the specification. For sufficiency, this will be determined by the functional features written into the claim. For inventive step, the technical contribution to be made plausible will be whatever non-obvious technical contribution the patentee says is made by the claimed invention.

Likewise, the Canadian Group (stating NO) believes that it is not desirable to require that “promises” in a patent’s description that do not directly support a claimed use must seem achievable for the person skilled in the art. The Canadian experience with the “promise of the patent” doctrine suggests that attributing weight to “promises” contained in patent descriptions fosters unreasonable patent construction and uncertainty in the law.

In contrast, the Dutch Group (stating YES) is of the view that if the inventive step of a claimed invention is based on a given technical effect, the latter should be achievable over substantially the whole area claimed. If the inventive step is based on a number of different effects, the patentee can only rely on those effects that have been made plausible. The applicant should in any case not be able to rely solely on an embodiment disclosing an effect that is not made plausible.

The Polish Group (stating YES) thinks that if at least one promise of the patent description, reflected in the patent claims, seems achievable for the skilled person and was not realized in the prior art with the use of same technical means, then other promises do not have to seem achievable for the skilled person.

**21) Should plausibility be a prohibition of “speculative” patent applications which do not (expressly) disclose a technical effect or concrete use e.g. of a chemical substance (the potential technical effect or concrete use rather remains speculative)?**

19 of the responding 32 Groups (60 %) stated YES, while 13 Groups (40 %) stated NO.

The Japanese Group (stating NO) thinks that it should depend on the type of invention whether disclosure of a technical effect or concrete use of a chemical substance is required. When the claimed invention is a new substance that is to be supplied, there is not a great deal of necessity to disclose its technical effect or concrete use. In the case of a use invention of a chemical substance, it is necessary to disclose its concrete use to satisfy the support or enablement

requirements, because the invention's contribution as compared with prior art is the provision of the concrete use of that substance.

**a) If yes, which standard should apply to determine a speculative filing? Which requirements should the applicant have to meet in order to reach a non-speculative filing?**

Please note that the Groups answering this Question 21 a) repeated their answers with regard to Question 22 a) below. Therefore, it is suggested to consider the answers to Questions 21 a) and 22 a) as a whole.

The Chinese Group thinks that applicant must submit experiments to preliminarily verify their effects and uses, such as compound interactions at molecular level, morphological or phenotypic changes at cell model level. Based on these experimental results, the person skilled in the art must be able to confirm that the compounds are able to achieve alleged effects or uses based on common knowledge, or a plurality of, for example 3, prior art documents from different authors in authoritative journals.

The Dutch Group is of the opinion that one needs to accept that the inventor cannot be expected to provide full proof of an effect by the date of application. However, the plausibility threshold must be sufficiently high to prevent applications for an invention that was not made or disclosed until after the application date. The amount of information that needs to be included in the application to support an effect should differ depending on how obvious the effect is that is described and/or claimed in the application for the average skilled person who reads the application with his common general knowledge. An effect and the substantiation thereof need for example not be explicitly mentioned in the patent specification if the effect and the achievement of this effect by the claimed subject matter are plausible to the average skilled person on the application date on the basis of his common general knowledge. However, stricter requirements must be set to the substantiation of an effect in the patent specification in the situation that an effect for the average skilled person reading the patent is not plausible on the basis of his common general knowledge on the application date. In that case, the application must contain some evidence that the effect in fact occurs. A way to prove this – and the preferred way in life sciences and chemistry - is by including data from experiments in the application. However, depending on the circumstances and the common general knowledge, a convincing scientific theoretical explanation in the application as to why the effect occurs may be sufficient to render it plausible. Finally, any effect relied upon for the assessment of the validity of the patent should be made plausible. Thus, a patent application that mentions various (advantageous) effects should render each of these effects individually plausible. An effect that is not made plausible cannot be taken into account when formulating the objective technical problem in the context of inventive step.

Independent Members (Taiwan) take the view that when the patent application does not (expressly) disclose a technical effect or concrete use, e.g., of a chemical substance, post-filing data demonstrating that the potential technical effect or concrete use is feasible may be submitted for being taken into

consideration in support of patentability. The applicant should have to meet the sufficiency of disclosure requirement in order to reach a non-speculative filing.

The Mexican Group thinks that the standard should be the same as the standard used to assess inventive step based on the prior art. In other words, if there is a piece of prior art which “speculates” about a certain result that is not expressly shown and that “speculation” is often used by the examiners to object inventive step or to establish obviousness, the same standard should apply to a speculation based on the teachings of the examined application. That is, if a patent application discloses something that is obviously derived from its detailed description for those skilled in the art, the description should be considered enabling and credible.

The Turkish Group is of the opinion that there should be a low-threshold test. The condition that should be considered as necessary and sufficient to approve the non-plausibility of an application could be the existence of a reference to common general knowledge or prior art in the priority document if priority right has been enforced or in the specification of the application. If the said conditions cannot be met, theoretical/applicable clarification and/or experimental data covered in the specification may be required.

The UK Group thinks that the standard should be set so as to ensure that the patentee has made a contribution to the art commensurate with the scope of the patent. The patent application ought to provide a basis for the skilled person, with his or her common general knowledge, to establish that the patentee has, in fact, made a technical contribution for which protection is claimed. In addition, the scope of the claims of the patent need to be in line with the technical contribution and should not be broader than the advance made by the patentee. The standard to be applied should be one of making the technical effect plausible (i.e. seeming reasonable or probable) to the skilled person rather the patentee being required to prove or demonstrate the technical effect. Accordingly, there ought to be no absolute requirement for experimental results/data in a patent application. The situation for each patent will be different and therefore it is difficult to give a more specific test. One indicium of the speculative nature of an invention is the inclusion of long lists of widely varied alternatives, especially if some are contradictory or non-operative. The presence of such lists in a patent should be taken into account and treated as a factor that tends to suggest that the patent is making speculative claims. Such an inference may be countermanded in relation to specific items in the list by appropriate specific information.

**b) What should be the consequence if a technical effect which is not expressly described in the specification is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification?**

The Danish Group thinks that if a technical effect is plausible because it was indeed implied or self-evident from the specification, then the consequence should be that the applicant or patentee is allowed to provide further experimental data to support or confirm that these technical effects are indeed realized.

Independent Members (Taiwan) take the view that if a technical effect which is not expressly described in the specification is nonetheless plausible because the

skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification, this technical effect produced by the technical feature which distinguishes over the prior art is *beneficial* for the claimed invention to have inventive step. Inter alia the Dutch Groups seconds the Independent Members in this conclusion.

In contrast, the UK Group is of the opinion that the result of the technical effect being only plausible from the skilled person's common general knowledge may impact the assessment of validity of the patent under other grounds (*such as inventive step*). However, if the technical effect is plausible, be that through the disclosure in the specification or from the disclosure and the skilled person's common general knowledge, this should be sufficient to overcome an objection of lack of plausibility.

**22) Should plausibility be a specific prohibition to refer to “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g. the description “predicts” that a specific experiment “will” prove a special property of the claimed compound?**

10 of the responding 31 Groups (30 %) stated YES, while 21 Groups (70 %) stated NO.

The US Group (stating NO) is of the view that there should be no prohibition against prophetic examples beyond what is presently required to comply with enablement, utility requirements, written description, and definiteness requirements. Prohibiting prophetic embodiments would create an unnecessary barrier to the timely filing of an application if the prophetic embodiment is predictable. If the prophetic embodiment proves inoperative, then embodiment is not patentable. The prohibition of a prophetic example would prevent the early disclosure of an invention, which is contrary to the purpose of the patent system.

The Swiss Group (stating NO) is of the opinion that plausibility should be understood as a standard in the assessment of enablement. The number and nature of examples, whether prophetic or not, is not determinative in the assessment of patentability. The question is rather, whether the application as a whole contains sufficient credible and enabling support to enable the skilled person to work the invention without undue burden. Thus, while the inclusion of prophetic examples (only) may increase the hurdle for a showing of enablement (in particular for unpredictable technologies), they do not necessarily deny plausibility as such.

In contrast, the Danish Group emphasises that a patent is not a hunting license and prophetic applications (shots in the dark) should be prohibited. In unpredictable or inherently complex areas, such as biotechnology, it should not be sufficient to merely assert that the technical problem the application purports to solve is indeed solved. In such cases verifiable and coherent evidence or reasoning should be present in the application as filed pointing towards a credible and plausible solution. In such cases it would also be problematic to allow patent applicants to rely solely on post-filed evidence to rebut inventive-step objections of this type. They should be required to consider carefully what evidence should be provided in an

application upon filing. In that way, the plausibility requirement provides an important requirement for patent quality.

**a) If yes, which standard should apply to identify prophetic examples?**

Please note that the Groups answering this Question 22 a) repeated their answers with regard to Question 21 a) above. Therefore, it is suggested to consider the answers to Questions 21 a) and 22 a) as a whole.

**b) Should all examples (or embodiments) need to pass this plausibility test? What should be the consequence if only some examples (or embodiments) do not pass the test?**

8 of the responding 30 Groups (25 %) stated YES, while 22 Groups (75 %) stated NO.

The Dutch Group (stating NO) points out that an effect must be rendered plausible in order to be taken into account when formulating the objective technical problem in the context of inventive step. Examples do not need to pass the plausibility test – they can be relied upon to render an effect plausible. To the extent that the examples are incredible or purely speculative, they cannot be used to render the effect plausible. This must be assessed on a case-by-case basis.

**23) What should be the relevant point in time for the plausibility test? What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?**

Except for Turkish Group (and some members of the Spanish Group), all Groups answering this question agree the relevant point in time should be the priority date.

**24) Should there be different plausibility tests for different types of claims (e. g. pure product/compound claims without functional feature, product claims including functional feature, second medical use claims, etc.)?**

9 of the responding 32 Groups (30 %) stated YES, while 23 Groups (70 %) stated NO.

**25) Who should have the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?**

As regards post-grant proceedings, almost all Groups agree that the opponent should have the burden of proof for lack of plausibility.

As regards pre-grant/application proceedings, about 50 % of the Groups are of the opinion that an “initial” burden of proof for lack of plausibility should be with the patent office; if the patent office fulfils this initial burden, the applicant should have the burden of proof for plausibility. The other 50 % of the Groups seem to agree that the application should have the full burden of proof for plausibility, without an “initial” burden of proof for lack of plausibility with the patent office.

**26) Please comment on any additional issues concerning any aspect of plausibility you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.**

The Japanese Group addresses the issue of plausibility of inventions that use artificial intelligence (AI). For example, an AI based program classifies images of a car driver into "Doze," "About to doze," and "Wakeful" and outputs a decision result. The model is trained with training data, i.e. a large number of driver images with correct labels (correct category). The model is enabled to perform a correct decision with a certain degree of accuracy. Therefore, it seems that a model would be able to make a correct decision if the model was repeatedly trained for any combinations of input data and decision result data. However, if the decision result data has no relation at all with the input data, the model will never be able to make a correct decision, regardless of how much it is trained. Thus, it has been a matter of concern to practitioners as to the required level of disclosure in the specification in order to satisfy a plausibility requirement.

The Dutch Group notes that the three big patent offices (USPTO, EPO, JPO) should agree on the basic principles regarding the plausibility requirement and the burden of proof. Moreover, the Group points out that one cannot properly deal with the issue of plausibility without taking the factor of post published evidence into account.

The Hungarian Group suggests that the issue of sufficient disclosure vs. fair scope of protection should be addressed in a future study question.

### **Industry sector views included in these proposals for harmonisation**

The following consultation with industry was reported:

- Semiconductor Manufacturing, Information Technology and Telecommunication (Independent Members Taiwan)
- CII, semiconductors, chemistry (Belgium)
- Electronic test equipment hardware and software, fast moving consumer goods (Singapore)
- Pharmaceutical industry (Poland, Philippines)
- Pharmaceutical industry and household appliances (Italy)
- Pharmaceutical and chemical industries (China, Estonia)
- Pharmaceutical and cosmetic industry (Spain)
- Pharmaceutical, electronics, and chemical industry (Finland)
- Pharmaceuticals, chemicals, automotive (USA)
- Pharmaceutical industry, cosmetics, energy, electronics and nuclear energy, defence and security (France)
- Pharmaceutics and biotech and university technology transfer offices (Mexico)
- Pharmaceutical industry, biotechnology and chemistry (Ecuador, Vietnam)
- Life sciences, telecoms and manufacturing (UK)
- Chemical industry (Brazil)

- Food manufacturing industry, organic chemical manufacturing industry (Japan)
- Energy, chemicals, biotechnology and life sciences (Denmark)

#### **IV. Conclusions**

While the clear majority of the responding Groups considers that harmonization regarding the plausibility issue is desirable, a slim majority of the Groups (55 %) is not in favour of the creation/definition of a stand-alone plausibility requirement.

In any case, the submitted Group Reports clearly show that the issues being discussed in this Study Question are of high practical relevance, and substantive harmonization of the handling of these issues seems desirable – be it through a plausibility standard or under one or more of the “conventional” patentability requirements such as inventiveness, sufficiency of disclosure, enablement, utility, etc.

Date: 10 July 2019