Study Guidelines

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2019 – Study Question

Plausibility

Introduction

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

2) 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.

Why AIPPI considers this an important area of study

3) There is currently no harmonized worldwide approach to plausibility. This causes legal uncertainty, increased complexity of global patent prosecution and hampers collaboration among the patent offices.

4) The issue of plausibility has a significant economic impact especially in the life science/pharma sector. It may create a disincentive to early filing of priority applications while the claimed technical effects are still under investigation or data collection (studies) is still ongoing.

Relevant treaty provisions

5) There is currently no formal legislation addressing the plausibility requirement. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC) and the European Directive 98/44/EC on the legal protection of biotechnological inventions do not contain provisions governing plausibility. Art. 29.1 TRIPs merely sets forth the general disclosure requirement stating that "*Members shall require*

that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art [...]."

6) The plausibility requirement is currently being developed by case law in some jurisdictions, see in more detail below.

Scope of this Study Question

7) 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.

8) 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.

9) 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.

Previous work of AIPPI

10) The requirement of sufficiency of disclosure has repeatedly been addressed by AIPPI, which led to the adoption of several Resolutions on this topic.

11) In the Resolution on Q69 – "Sufficient description of the invention" (Munich, 1978), AIPPI resolved, "*The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The person skilled in the art is skilled in the art corresponding to the technology with which the invention is concerned*."

Also, "*the description must be clear and complete*", which means that it "*shall supply all which is necessary, not only to understand the invention, but also to carry it out or implement it.*" In order to be complete, "*it should not include any obscurity or ambiguity.*"

However, "*difficulty in carrying out the invention may not be confused with obscurity, and the capacity of the person skilled in the art must correspond to the nature and the degree of the invention*."

Furthermore, the person skilled in the art must be enabled to carry it out, which means that the description "*discloses the constituent elements of the invention and the instructions adequate to enable a person skilled in the art to put the invention into effect by the application of his skill and knowledge*." Additionally, it states "*that an invention cannot be considered as inadequately described on the sole ground that it is difficult or imperfect.*" This was also emphasized in the Resolution on

"Added Matter: the standard for determining adequate support for amendments" (Milan, 2016).

12) In addition to confirming the core statement of the Resolution on Q69, the Resolution on Q142 "Breadth of claims, support by disclosure and scope of protection of patents" (Rio de Janeiro, 1998) particularly states that "the *criteria [for the drafting of claims and disclosure] are applicable to all inventions, regardless of the technical field involved and whether the invention can be said to be of 'pioneer' status*."

13) Moreover, the Resolution on Q213 "The person skilled in the art in the context of the inventive step requirement in patent law" (Paris, 2010) defines the person skilled in the art as having "*at least the following characteristics:*

- This person possesses common general knowledge as well as knowledge in the field (or fields) to which the invention relates that the average person in that field (or fields) would be expected to have or which would be readily available to that average person through routine searches;

- This person possesses the skills that are expected from the average person in the field (or fields) to which the invention relates.

- This person is able to perform routine experimentation and research and can be expected to obtain predictable solutions as compared to the prior art."

14) The Resolution on Q82 "Patent protection for biotechnological inventions" (Rio de Janeiro, 1985) and the Resolution on Q150 "Patentability requirements and scope of protection of expressed sequence tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes" (Sorrento, 2000) recommend that the criteria for sufficiency of disclosure should also apply for biotechnological inventions. A deposit of a living organism or other biological material is not required; however, it should always be considered as completing the requirement of sufficient disclosure particularly in relation to repeatability of the invention.

15) In the Resolution on Q180 "Content and relevance of industrial applicability and/or utility as requirements for patentability" (Geneva, 2004), AIPPI notes the necessity for "*a harmonized patentability criterion ['practical applicability'] in addition to novelty and inventive step and in replacement of industrial applicability and utility*", which "*should not be construed to introduce new patentability requirements which do not exist under the concepts of industrial applicability or utility*." Therefore, the Resolution on Q180 addressed a similar question as this Study Question, however, without overlap to its specific scope.

16) The AIPPI 2017 Position Paper "AIPPI's Resolutions Relating to Sufficiency of Disclosure" summarizes the above-mentioned Resolutions.

17) At the Sydney Congress in 2017, AIPPI held a panel session titled "Sufficiently plausible" that highlighted the global emergence of plausibility as a requirement and analyzed significant differences in the approaches taken in the USA, Canada, Europe and China.

18) Lastly, thematically related to this topic, AIPPI published a position paper titled “Recommendations on the use of post-filing data in support of inventive step” in 2017 and passed the Resolution on “Use of post-filing data in support of inventive step/non-obviousness" at the Cancun Congress in 2018.

Supporting the use of post-filing data in support of inventive step/non-obviousness, the 2018 Cancun Resolution states that “*in pre-grant proceedings before a national or regional patent office, patent applicants should be able to support inventive step/non-obviousness of claimed subject-matter by relying on Post-filing data showing at least one property or effect of the claimed invention, in particular in situations where the property or effect is already described in or is apparent from the patent application, either explicitly or implicitly*.”

In addition, patent applicants should be able to further support a technical effect or property, in order to support inventive step/non-obviousness, by either referring in general terms to prior art or by specifically providing a comparison with the prior art.

Analogously, patent owners should also be able to rely on Post-filing data in post-grant proceedings such as post-grant oppositions or post-grant invalidity proceedings, either before a national or regional patent office or before a national or regional court.

However, it is important to note that the use of post-filing data is not within the scope of this Study Question.

Discussion

19) As regards the case law of the Boards of Appeal of the EPO, e.g. the first decision stating that an effect must be “credible” is AgrEvo of 12.9.1995 – T939/92, which is still considered as the lead decision in this debate. The term “plausibility” was first introduced by the decision Factor-9/JOHN HOPKINS of 28.6.2005 – T1329/04. Further decisions explained what needs to be made plausible, e.g. Neutrokine/HUMAN GENOME SCIENCES of 21.10.2009 – T18/09, Arch Development Corp of 2.12.2010 – T1642/07, and Dasatinib/BMS of 01.02.2017 – T488/16.

20) In the decision Factor-9/JOHN HOPKINS of 28.6.2005 – T1329/04, the problem to be solved by the claimed invention was to “isolate[e] a further member of the TGF-Beta superfamily”. The subject matter of the claim was a specific member of the TGF-Beta superfamily called TGF-9. The original application did not disclose a functional characterization of TGF-9. At the priority date, there was no evidence available yet showing that the claimed compound is actually a growth differentiation factor, i.e. it was merely a “speculation” that this property is given. The Board therefore held that there was not enough evidence in the application to make “at least plausible” that a solution was found to the problem which was purportedly solved. It states:

"The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve." (emphasis added)

21) It seems important to note that the Board rejected patentability of the claimed invention under the inventive step requirement (Article 56 EPC). One may derive from this decision that the facts in support of inventive step must be supported by evidence available at the priority date, while speculations or merely prophetic examples seem to be inadmissible in support of inventive step.

22) Some national European courts adopted variations of this plausibility requirement (e.g. House of Lords, Conor Medsystems Inc. v. Angiotech Pharma, Inc. – [2008] UKHL 49, and Patents Court of England and Wales of 16.11.2015 – Actavis Group PTC EHF & Anor v Eli Lilly and Company [2015] EWHC 3294 (Pat), and the decision of the Court of Appeal of The Hague, 07.11.2017, LEO Pharma v. Sandoz, 200.195.459/01), while most other European national courts seem to be hesitant to introduce the requirement into national practice.

23) Under Canadian patent law, the utility of the claimed invention must be demonstrated or "soundly predicted". The patent as filed must have (1) an actual basis for prediction, and (2) an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis.

24) It seems to be the broader rational of these doctrines to prevent excessive "land claiming" by patent applications on subject matter which have a high potential of commercial use, but which require further study to evaluate this potential. Recognizing and disclosing the potential use as such is not sufficient to support inventive step. The patent shall be rather awarded to the applicant actually providing the evidence that the contemplated use is indeed feasible.

25) On a more abstract level, this plausibility requirement therefore echoes a fundamental discussion in patent law, namely the question whether availability of patent protection aims to incentivize an early disclosure of technical achievements for the benefit of a dynamic development of the overall economy, or rather the disclosure of "completed" inventions (which may involve a mandatory disclosure of a "best mode").

26) In the history of patent law, this discussion appeared under various titles. Before the advent of the current plausibility discussion, this theme was, for example, vigorously discussed in the context of patentability of expressed sequence tags (ESTs). An EST is a short sub-sequence of a cDNA sequence. ESTs may be used to identify gene transcripts and to determine gene-sequences. Patent applications on ESTs typically did not disclose the gene-sequence (in particular not its function) the claimed EST relates to; the applicant rather "speculated" that the claimed EST happens to relate to an economically important gene-sequence, which would then

fall in the scope of protection of the EST claim. These types of filings led to a controversial worldwide patentability debate. In Europe, this discussion was ultimately ended by Recital 23 of the Directive 98/44/EC on the legal protection of biotechnological inventions stating: "*Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention*." This recital is nowadays reflected by Rule 29 (3) EPC, stating: *"The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."*

27) The ongoing plausibility discussion shows that there is still a lack of consensus as to this quite fundamental question. Therefore, it seems timely to revisit this topic under the flag of "plausibility". In this context, one also should consider the strong incentive for an early disclosure provided by the first-to-file system, which penalizes a "diligent" applicant filing a perfectly "complete" invention if they are no longer the first applicant.

28) As mentioned above, the overall discussion within this Study Question shall be limited to three distinct sub-issues:

- The patent application describes a technical effect of the claimed invention which appears non-credible to a person having ordinary skill in the art (or even to an expert in the field). This may be, for example, because the described effect contradicts the common perception of in the relevant technical field and/or is a surprising effect.

- The patent application does 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 ("speculative" patent application).

- The patent application merely contains "prophetic" examples (or embodiments) 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.

You are invited to submit a Report addressing the questions below. Please refer to the 'Protocol for the preparation of Reports'.

Questions

I. Current law and practice

Please answer all questions in Part I on the basis of your Group's current law.

1) Does your law in general provide a plausibility requirement?

2) Is the plausibility requirement, if any, a stand-alone requirement or is it integrated into another requirement (e.g. inventive step)?

3) Are there any statutory provisions that specifically apply to plausibility? If yes, please briefly explain.

4) Please briefly describe the general patentability requirements in the statutory law of your jurisdiction that are or would be relevant to the issue of plausibility.

5) Under the case law or judicial or administrative practice in your jurisdiction, are there decisions or rules that specifically apply to plausibility? If yes, please briefly explain.

6) Please briefly describe the general patentability requirements under the case law or judicial or administrative practice of your jurisdiction that are or would be relevant to the issue of plausibility.

If there is no explicit or implied plausibility requirement in the law or under the judicial or administrative practice in your jurisdiction, please skip the below questions and proceed directly to question 15.

7) Can the plausibility requirement be regarded primarily as a "credibility" requirement, i.e., a requirement applying to patent applications that describe a technical effect that appears non-credible, e.g., because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?

   a) If yes, is the credibility determined from the perspective of a person having ordinary skill in the art, or from the perspective of an expert in the field?

   b) If the relevant perspective is the person having ordinary skill in the art, why is a "credible" technical effect not also obvious at the same time?

   c) Do <u>all</u> the promises of the patent description have to seem achievable for the person skilled in the art?

8) Can the plausibility requirement be regarded primarily as 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)?

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

   b) 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, why was the technical effect not obvious at the priority date?

9) Can the plausibility requirement be regarded primarily as specific prohibition against “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g., the description merely “predicts” that a specific experiment “will” prove a special property of the claimed compound?

   a) If yes, which standard does apply to identify a prophetic example? Must the applicant submit test data etc. to support examples (unless self-evident)?

   b) Do <u>all</u> examples (or embodiments) need to pass this plausibility test? What is the consequence if only some examples (or embodiments) do not pass the test?

10) Is it possible to make a clear distinction between the above-mentioned aspects (as set out in the questions 7-9 above) or do they merge into each another?

11) What is 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?

12) Are there different plausibility tests for different types of claims (e.g. pure product/compound claims without a functional feature, product claims including a functional feature, second medical use claims, etc.)?

13) Who has the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?

14) Please comment on any additional issues concerning any aspect of plausibility that is being regulated by your Group’s law/practice you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.

II. Policy considerations and proposals for improvements of your Group's current law

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

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”)?

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?

III. Proposals for harmonization

Please consult with relevant in-house / industry members of your Group in responding to Part III.

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

If YES, please respond to the following questions without regard to your Group's current law.

Even if NO, please address the following questions to the extent your Group considers your Group's current law could be improved.

19) Should there be a plausibility requirement?

If no, please briefly explain why and then please also answer the following questions assuming there is a plausibility requirement.

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?

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?

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

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)?

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?

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?

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?

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

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?

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?

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.)?

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

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.

27) Please indicate which industry sector views provided by in-house counsel are included in your Group's answers to Part III.