2019 Study Question

Submission date: May 22, 2019

Jonathan P. OSHA, Reporter General
Ari LAAKKONEN and Anne Marie VERSCHUUR, Deputy Reporters General
Guillaume HENRY, Ralph NACK and Lena SHEN, Assistants to the Reporter General

Plausibility

Responsible Reporter(s): Ralph NACK

National/Regional Group	Hungary
Contributors name(s)	Árpád PETHÖ, Mónika BIACS, Zsuzsanna BUZÁS-NAGY, András CSERNY, Daisy MACHYTKA-FRANK, Imre MOLNÁR, Éva SOMFAI, Zsolt SZENTPÉTERI, József TÁLAS
e-Mail contact	kereszty@godollepat.hu

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?**

No

Please Explain

There is no direct plausibility requirement in the Hungarian Patent Act. However, the sufficiency requirement of the Hungarian Patent Act can be interpreted in such a way that it comprises an indirect plausibility requirement, i.e. it prohibits the granting of patents on speculative inventions, which are not plausibly supported in the description. Case law also tends to support this interpretation. Furthermore, the requirement of plausibility is also indirectly included in all other fundamental patentability requirements (like industrial applicability, novelty and inventive step), as the features of the claimed invention distinguishing it from the prior art and enabling its industrial applicability must be disclosed plausibly in the specification.

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

No

Please Explain

As there is no direct plausibility requirement, it cannot be a stand-alone requirement. The sufficiency requirement of the Hungarian Patent Act can be interpreted in such a way that speculative and not plausibly supported inventions are not patentable as the POSA is not able to carry out them on the basis of the description, the drawings and the claims. Furthermore, all further fundamental patentability requirements (like industrial applicability, novelty and inventive step) must be plausibly fulfilled by the claimed invention, i.e. the features of the claimed invention

distinguishing it from the prior art and enabling its industrial applicability must be disclosed plausibly in the specification.

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

No

Please Explain

There is no concrete statutory provision in the Hungarian Patent Act that would specifically (directly) apply to plausibility.

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.**

The closest statutory provision seems to be Article 60 (“Disclosure of invention, claims and abstract”), particularly paragraph (1) of this Article, the English translation of which reads as follows:

“A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings.”

Furthermore, the claimed technical solution must be disclosed in the description in a manner that its difference from the state of the art (novelty), its inventiveness and its industrial applicability must be plausible for the person skilled in the art on the priority / filing date.

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**

Yes

Please Explain

There are no specific rules that apply to plausibility, however there are decisions of the Hungarian Intellectual Property Office (HIPO) rejecting patent applications because of insufficiency by excessive claim breadth on the grounds of Article 60 paragraphs (1) and (3) as well as for lack of inventive step on the grounds of Article 4. There are Court decisions dealing with issues of insufficiency regarding different types of patent claims. In the case of second medical use claims the main issue is, what kind of data should be presented in order to sufficiently demonstrate, that the compound is effective for the treatment of the claimed disease, i.e. was the problem plausibly solved on the priority / filing date. However, our respective court practice is quite divergent in this regard.

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.**

The general patentability requirements that are most relevant to the issue of plausibility under Hungarian case law are the sufficiency of disclosure and support according to Articles 60 (1) and (3) as well as inventive step according to Article (4) of Hungarian Patent Act. The implied plausibility requirement in these patentability requirements reflected in the Guidelines for patent examination of the HIPO in Chapter III. clarifying the general rules of substantive examination. For example, in point 4.3.1. detailing the assessment of inventive step, in the context of selection inventions and synergistic combinations the Guidelines states that the existence or absence of an inventive step can be determined by examining the technical effect of the solution. This means that if the patent application does not plausibly disclose the surprising new technical effect, the inventive step cannot be acknowledged.

Chapter III. point 8. relating to the disclosure requirements points out, that the sufficiency of the disclosure is important for the applicant, because patent protection can only be claimed in accordance with the disclosure in the specification. The description and the drawing shall contain sufficient and plausible information for a person skilled in the art to carry out the invention, and it should be clearly understood from the description, how the inventor contributed to the state of the art.

In the case of pharmaceutical inventions, it is essential to plausibly substantiate the newly discovered therapeutic effect, for example by pharmacological tests and their results.

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?**

No

Please Explain

No, the plausibility requirement cannot be regarded primarily as a "credibility" requirement, especially not in the context appearing in Question 7. As mentioned also above (see the answers to Questions 1 and 2), the Hungarian Patent Act does not provide a direct plausibility requirement but only an indirect one, mostly implied in the sufficiency requirement regulated by Art 60 (1) and (3), which can be interpreted to exclude speculative inventions from the scope of patentable inventions. However, in terms of the Patent Act, the sufficiency requirement does not exclude the patentability of inventions where the disclosed effect contradicts the common perception in the relevant technical field and/or has a surprising effect (provided that the effect is sufficiently disclosed and supported by the specification). This is also supported by Chapter III point 4.3.2.11. of the Guidelines for patent examination of the Hungarian Intellectual Property Office disclosing that an invention has to be considered as based on inventive step, if the features distinguishing the invention from the prior art result in overcoming a common perception in the relevant technical field, and also by point 4.3.1 of the Guidelines stating the invention is based on inventive step if the characteristics distinguishing the invention from the prior art involve a new surprising effect.

7.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?**

7.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?**

7.c **Do all 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)?**

Yes

Please Explain

Yes, the indirect plausibility requirement comprised within the sufficiency of disclosure requirement can primarily be regarded as a prohibition of “speculative” patent applications. Chapter 8 of the HIPO Guidelines says, *inter alia*, the following in this regard: “The description must disclose in detail at least one embodiment of the invention (with the description of its functioning and effects). … The description must disclose all essential features that are required for practicing the invention in such a detail that practicing the invention be obvious for the POSA. In the case of inventions belonging to the chemical field, rendering the identified effects plausible is also inevitably necessary for meeting the requirement of sufficient disclosure.” The requirement of inventive step also comprises a requirement that the technical problem set by the application must be plausibly solved (clearly speculative examples/embodiments are not considered to support that the problem is plausibly solved).

8.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?**

Our examination practice or case law does not provide for any specific standard for determining a “speculative filing”. Generally, only filings which clearly fail to comprise a sufficient disclosure for the POSA and filings clearly not supporting that the technical problem is plausibly solved are objected to.

8.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?**

A technical effect being plausible on the basis of a patent specification is not necessarily obvious. If a technical effect is only implied in or self-evident from the specification itself, it might not be obvious upon the state of the art without knowing the specification. The claimed solution must be plausible for the POSA in the knowledge of the patent specification.

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?**

Yes

Please Explain

As provided in point 8) above, the plausibility requirement can primarily be regarded as a prohibition of “speculative” patent applications. Applications comprising only prophetic examples as examples to support not reasonably predictable property/effect usually form a subclass of “speculative” patent applications (if, however, the property/effect is reasonably predictable, then the claimed invention is likely to face a lack of inventive step objection). Prophetic examples typically occur in the chemical/biotech field. As mentioned in point 8), according to the HIPO Guidelines, in the case of inventions belonging to the chemical field, rendering the newly identified effects plausible is also inevitably necessary for meeting the requirement of sufficient disclosure. Prophetic examples alone are not suitable for rendering the identified effects plausible.

9.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)?**

A prophetic example is an example which does not comprise the results of the test/process described therein. Typically prophetic examples are examples describing test methods without giving the results of the tests. A prophetic example, i.e. an example without results can be considered as specifying an effect, but not proving same.

9.b **Do all examples (or embodiments) need to pass this plausibility test? What is the consequence if only some examples (or embodiments) do not pass the test?**

No

Please Explain

Embodiments not made plausible by the disclosure have to be excluded from the scope of the claims.

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?**

No

Please Explain

It is not possible to make a clear distinction between the aspects of questions 7-9, as it follows already from the above. Also, prophetic examples do not contribute to credibility.

11 **What is the relevant point in time for the plausibility test?**

From the viewpoint of novelty the priority date is the relevant point in time, from the viewpoint of disclosure, the relevant point in time is the filing date.

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?

If the technical effect of an invention appears plausible at the priority date, but later it proves to be wrong, then the disclosure is considered insufficient. If the technical effect of an invention appears not plausible at the priority date, but it proves to be plausible at the filing date, then the priority may be lost.

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.)?**

No

Please Explain

There are no generally accepted plausibility tests for different types of claims in the Hungarian practice but the indirect plausibility requirement is considered differently with respect to different types of claims. A per se claim to a pharmaceutical composition containing a new chemical entity or a first medical use type claim does not need to be supported by evidence of its suitability for its intended medical use in the same way as second and further medical use type claims. The less pioneering the invention is, the more rigorously plausibility is required.

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

Generally speaking, the HIPO examines the facts of the case *ex officio* and the examination cannot be limited to the allegations of the parties [Patent Act, Art. 47(1)]. On the other hand, in invalidity proceedings, the HIPO examines the facts of the case within the limits set by the parties' motions, statements and allegations, based on the information substantiated by the parties [Patent Act, Art. 47(2)]. The HIPO's decision must be based solely on such facts and evidence that the parties were enabled to comment on [Patent Act, Art. 47(3)].

According to the relevant legal literature, where an authority or office examines the facts *ex officio*, the burden of proof generally lies with the authority or office. On the other hand, this general rule does not oblige the Office to gather such information or pieces of evidence that the applicant is required to submit. Furthermore, in invalidity proceedings, the burden of proof lies with the 'opponent' (the party initiating the invalidity proceedings).

With respect to the aforementioned general rules, and taking into consideration that plausibility is not a standalone requirement but it is built in general patentability requirements such as sufficient disclosure and inventive step, the following rules can be deducted in relation to proving (lack of) plausibility:

(a) first and foremost, the applicant has the burden of proof for plausibility in a sense to comply with the indirect plausibility requirement in the patent application (when filing);

(b) if the Office further challenges plausibility, the burden of proof in this respect lies with the Office;

(c) in invalidity proceedings, the 'opponent' (the party initiating the invalidity proceedings) has the burden of proof for demonstrating the lack of plausibility.

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.**

Our case law is now addressing the special issue of the required plausibility of sufficient disclosure vs. fair scope of protection to be granted in the case of a second medical use type invention (within the framework of the famous Lyrica / pregabalin pain litigation, which is litigated parallel in many jurisdictions with similar factual bases and plausibility is a major issue in many places) but the issue is not settled yet finally. Nevertheless, this special issue might worth international discussion. This is because, as a consequence of the social agreement behind the patent systems (i.e. the so called "patent bargain"), not all types of inventions are required to be plausibly supported throughout the whole grantable scope. For example, the claim type "substance X for use as a medicament" is allowable in many jurisdictions for first medical indication type inventions, even though no patent specification can plausibly support that substance X is effective against all types of disorders. Plausible support may only be requested throughout the whole claimed scope in the case of clearly non-pioneering inventions (e.g. new pharmaceutical formulations, new dosage regimens) where the social agreement behind the patent system, which manifests in the patent practice, does not allow broader than supported scope to be claimed as an incentive to support innovation. In the Lyrica case in Hungary it is argued among the parties whether a second medical use invention can be considered pioneering at all (e.g. if it concerns a use of a substance in a medical field being rather distant and separate from that of the first medical use disclosure of the same substance) or all second medical use inventions are to be considered non-pioneering for which plausible support must be required throughout the whole claimed scope. The HIPO supported the first approach while the Metropolitan Court of Budapest was in favor of the second one. The decision is under appeal.

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.**

No

Please Explain

There is no direct regulation on plausibility in our current patent law and we do not think that there is a need for that. As it can be seen from the first part of our report, we think that plausibility is an indirect requirement being mostly present in the sufficient disclosure and inventive step requirements but it is to be assessed differently with respect to different type of inventions (i.e. pioneering and less pioneering inventions). Consequently, we think that the correct assessment of the requirement of plausibility should be rather regulated at the level of case law also addressing the different plausibility requirements for different types of inventions.

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")?**

Yes

Please Explain

Hungary has always had a "first to file" patent system without "best mode" requirement, which by nature incentivize the early disclosure of technical achievements with which we agree. Consequently, we think that a too severe plausibility requirement would be counterproductive in our patent system.

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?**

No

Please Explain

The present indirect plausibility requirement as it is applied usually does not much interfere with the incentive for an early disclosure provided by the first-to-file system and we are against any more severe assessment of this indirect requirement in our patent 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.**

No

Please Explain

We think that no general harmonization of the plausibility requirement at the level of patent law is desirable. We think that having a comprehensive case law on this issue would be desirable and we think that the case law of the EPO and other specialized European courts is getting more and more comprehensive (even though it cannot yet be called fully unified).

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.**

No

Please Explain

As we explained above at Question 15, we think that the correct assessment of the requirement of plausibility should only be regulated at the level of case law.

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?**

No

Please Explain

No (see our response re Question 7).

20.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?**

20.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)?

Yes

Please Explain

21.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?

The disclosed effects of the invention distinguishing it from the prior art must be credible for the POSA on the basis of the disclosure given in the specification and in the prior art.

21.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?

In such a case the plausibility requirement should be acknowledged as fulfilled.

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?

Yes

Please Explain

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

A prophetic example is an example without definitely given, plausible test results or a plausibly demonstrated achieved goal.

22.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?

No

Please Explain

The embodiments failing to pass the plausibility test should be excluded from the scope granted.

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?**

From the viewpoint of novelty the priority date should be the relevant point in time, from the viewpoint of disclosure, the relevant point in time should be the filing date. If the technical effect of an invention appears plausible at the priority date, but later it proves to be wrong, then the disclosure should be considered insufficient. If the technical effect of an invention appears not plausible at the priority date, but it proves to be plausible at the filing date, then the priority should be lost.

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.)?**

Yes

Please Explain

The plausibility requirement should be considered differently with respect to different types of claims. The less pioneering the invention is, the more rigorously plausibility should be required.

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

(a) First and foremost, the applicant should have the burden of proof for plausibility in a sense to comply with the indirect plausibility requirement in the patent application (when filing);

(b) if the Office further challenges plausibility, the burden of proof in this respect should lie with the Office;

(c) in invalidity proceedings, the ‘opponent’ (the party initiating the invalidity proceedings) should have the burden of proof for demonstrating the lack of plausibility.

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 special issue of the required plausibility of sufficient disclosure vs. fair scope of protection to be granted (e.g. in the case of second medical use type inventions) would be interesting to address. This is because, as a consequence of the social agreement behind patent systems (“patent bargain”), not all types of inventions are required to be plausibly supported throughout the whole grantable scope. For example, the claim type “substance X for use as a medicament” is allowable in many jurisdictions for first medical indication type inventions, even though no patent specification can plausibly support that substance X is effective against all types of disorders. Plausible support may only be requested throughout the whole claimed scope in the case of clearly non-pioneering inventions (e.g. new pharmaceutical formulations, new dosage regimens) where the social agreement behind the patent system, which manifests in the patent practice, does not allow broader than supported scope to be claimed as an incentive to support innovation.

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

Pharma and biotech.