2019 Study Question

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Plausibility

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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

The term "plausibility" is not directly defined in the Chinese Patent Law.

However, corresponding to the requirement of "sufficient disclosure" of application documents in Article 26, paragraph 3, of the Chinese Patent Law and the requirement of "claims should be supported by description" in Article 26, paragraph 4 of the Chinese Patent Law, the Guidelines for Patent Examination have corresponding requirements for similar concepts of "reasonable predictability", and specifically, judging the "reasonable predictability" of the claimed technical effect is required in the following aspects:

(i). On sufficient disclosure: At least one technical effect of the claimed invention should be recorded in the description or can be derived directly from the prior art and the application document. In the field of chemistry/biology/pharmacy etc., the effect of this technology usually should be verified by experiment recorded in the description. It is usually not enough to satisfy the requirement of sufficient disclosure only on a plausibility, allegation or reasonable predictability.

(ii). On claim support by the description, If part of the technical solutions of the claimed invention (or some examples/embodiments) has met the sufficient disclosure requirement, i.e., the technical effect to be achieved by the technical solution has been verified, only when those skilled in the art can "reasonably predict" the other technical solutions in the claim have technical effects identical or similar to the one experimentally verified, the said other technical solutions in the claim can be supported by the description.

Generally, experimental verification of the other technical solutions is not necessary if they are sufficiently similar to the one that has been verified. However, if any of the technical solution with an unverified technical effect is found to have no technical effect as that have been verified as said above, it may be declared null and void because it is not supported by the description (see the Decision No. 36170 of China

Patent Re-Examination Board on 3 August 2018 on the examination of invalidation).

For more specific description similar to "plausibility" in the Patent Examination Guide, please see the answer to Question 3) below.

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 mentioned above, the requirement of "reasonable predictability" is integrated into the evaluations on the sufficient disclosure and the claim support by description. However, in different evaluations, the requirements for "reasonable predictability" are not exactly the same.

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

No

Please Explain

There is no specific provision on plausibility in The Chinese Patent Law. However,

(i) Corresponding to the requirement of sufficient disclosure in Article 26, paragraph 3, of the Chinese Patent Law, the Guidelines for Patent Examination deal with provisions similar to "plausibility".

Article 26, paragraph 3, of the Chinese Patent Law stipulates that " The description shall set forth the invention or utility model in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out.". In response to this provision, the Patent Examination Guide stipulates that "if a person in the art is unable, on the basis of the prior art, to predict that an invention can achieve the said use and/or its technical effect, the description shall also record qualitative or definitive experimental data that, for the person skilled in the art, the technical solution of the invention can achieve the said use and/or the technical effect as desired. See Part II, Chapter div 10, div 3.1 (3), paragraph 2 of the Guidelines for Patent Examination.

(ii) Article 26, paragraph 4, of the Chinese Patent Law requires that "the claims shall be supported by the description and shall define the extent of the patent protection sought for in a clear and concise manner.". That is to say, the claim should be supported by the description. Corresponding to this provision, Part II, Chapter 2, div 3.2.1 of the Guidelines for Patent Examination contains the following relevant provisions similar to "plausibility":

(a) If a person in the art can reasonably predict that all equivalent alternatives or apparent variants of the embodiments given in the description will have the same performance or use, the applicant shall be allowed to generalize the scope of the claim to cover all of their equivalent alternatives or apparent variants.

(b) If a generalization of a claim contains the content speculated by the applicant and its technical effect is difficult to determine and evaluate in advance, it should be considered that the generalization is beyond the scope of the disclosure of the description.

(c) If a generalization of a claim gives a person skilled in the art any reason to suspect that one upper generalization or one or more of the lower concepts or alternatives contained in the upper generalization or parallel generalization cannot solve the technical problems to be solved by the invention or utility model and achieve the same technical effect, such claim shall be deemed to have not been supported by the description.

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.**

For example, the answers to questions 1) to 3, the sufficient disclosure and the claim support by the description deal with "reasonable expectations".

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

China is a country of statute law rather than case law.

The Supreme People's Court of China has a similar judgment to the plausibility in an administrative litigation:

In the administrative review judgement No. 8 (2014) of the Supreme people's Court of China, it pointed out that the identification of compounds is necessary for the claims for new compounds, but the confirmation of the structure of compounds has not been completed in this case. Although the synthetic method of the compounds is recorded in the description, it still cannot satisfy the requirement of sufficient disclosure. requirements, even if the compound can be obtained by the synthetic method described in the description or even if it could be proved afterwards that the compound can indeed be obtained by the method.

In this case, it is unacceptable to rely solely on reasonable predictability, because the structure of the compound cannot be identified. Referring to the principle established in this case, solely on the basis of reasonable predictability or plausibility of technical effects, it is generally unacceptable for sufficient disclosure in the fields of biology, chemistry and pharmacy.

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 requirements related to plausibility in Chinese judicial or administrative practice are consistent with the above questions 1) to 4).

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?**

Yes

Please Explain

The requirement of plausibility is basically the same as that of credibility.

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?**

Yes

Please Explain

The person skilled 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?**

Yes

Please Explain

The technical effect of "credible" is not necessarily obvious, because the judgment basis of credibility and non-obviousness is different.

For the person skilled in the art, the judgement of "credibility" is based on the contents disclosed in the description of the present invention and the prior art. However, when judging non-obviousness, that is, when judging inventive step, it is only based on the prior art.

7.c **Do all the promises of the patent description have to seem achievable for the person skilled in the art?**

No

Please Explain

Not all promises of the patent description must be fulfilled, for example, the fulfilment of at least some of them usually meets the requirement of sufficient disclosure.

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

If the speculative patent application is not able to be verified as true, a protection for the speculative patent application is unfair.

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?**

"Speculative application" generally refers to an application that does not disclose any substantive effect, or when it discloses a technical effect, but the technical effect has not been verified by experiments, while whether the technical effect exists or not must be verified by experiments.

Usually, as a non-speculative application, it means that a person skilled in the art can confirm that the application can achieve the technical effects as recorded. For example, in the field of machinery, a person skilled in the art can confirm their technical effects through the connection relationship etc. between structures and components, and in the fields of chemistry, pharmacy and biology, experimental data are usually needed to be provided to verify their technical effects.

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?**

As stated in Question 7-b), the basis for judging plausibility and non-obviousness is different.

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

Giving protection for the claim supported by the "prophetic" examples is unfair.

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)?**

Examples without recording experimental data or results to prove the alleged technical effect are usually prophetic examples.

Applicants usually have to submit test data and so on in the description to support the example. The test data post filed in the application usually cannot support the prophetic example.

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

Not all examples (or embodiments) need to pass this plausibility test, usually only the examples (or embodiments) covered by the claims need to pass the test.

If some examples (or embodiments) fail to pass the test, the technical solutions corresponding to those embodiments that fail the test cannot be granted.

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

There is no clear distinction. There is no clear boundary between them.

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

The time point of plausibility test should be the application date (or priority date if any).

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 to be plausible on priority date but later proves to be wrong, it may be rejected in the examination procedure or invalided in the invalidation procedure after grant.

If the technical effect of an invention does not appear to be plausible on the priority date, and if it is rejected in the examination procedure, there is no remedy in the later period.

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

Plausibility test aims at the effects recorded in the description or directly obtained, and does not distinguish the types of claims.

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

During the examination of patent applications, the applicant is mainly responsible for proving the plausibility (reasonable predictability).

In the process of patent invalidation, the invalidation petitioner is responsible for proving that the patent lacks plausibility (reasonable predictability), and the patentee can refute the claim of the invalidation petitioner by giving counterevidence.

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.**

In the examination, if the examiner has objection on the plausibility of the application, he/she should give reasonable reasons and give preliminary proof.

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

As far as the Chinese Patent Law is concerned, the relevant provisions of plausibility can hardly be embodied in the law at present.

However, in the Guidelines for Patent Examination, the criteria for judging plausibility or reasonable predictability should be refined and clearly (relatively clearly) defined in accordance with the different provisions of the Chinese Patent Law, so as to form a unified provision that everyone can easily refer to. Now the criteria are largely determined by the judgement of the examiners, and depend on specific cases.

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

Both.

The Chinese Patent Law is a first-to-file system, and adopts a system of early publication and deferred examination for invention patent applications. There is no mandatory requirement for "best mode". However, it is not encouraged to apply too early before completing the

required experimental work to prove the effectiveness or use of the relevant technology, especially in the fields of biology, chemistry and pharmacy.

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 Chinese Patent Law does not specify the plausibility, but there are reasonable predictability requirements similar to the plausibility in terms of "sufficient disclosure" and "claim support by the description", and there is no obvious interference with the incentives for early publication stipulated by the first-to-file system.

For example, it does not take too much time to verify technical effects to meet the minimum level of the requirement of patentability in comparison with the 20-year protection period for invention patent.

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.**

Yes

Please Explain

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.**

Yes

Please Explain

Some situations should exist, such as some technical solutions of Marcus claims. Even without specific experimental data, a grant claim on "plausibility" is conducive to encouraging innovation.

While in some cases, grant patents on the "plausibility" (e.g. US08859741B2, US8563698B2, etc.) may lead to some enterprises wanton a "horse-racing enclosure" to occupy unfair claim scopes. Especially, since the technological level of Chinese pharmaceutical industry lags far behind that of developed countries, if technologically advanced enterprises obtain exclusive right for such patents without sufficient experimental data through early basic research, it may lead to technological monopoly. It will seriously restrict the development of Chinese pharmaceutical enterprises. Even if in a post-grant procedure, such patents could be revoked through invalid procedures, in order to prove that it is a wrong grant patent on "plausibility", it would also increase the burden of technologically backward enterprises on their expenditure of the human, material, financial and time resource, and thus its disadvantages outweigh the advantages.

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?**

Yes

Please Explain

It should be a credibility.

The essence of plausibility is to judge whether technical solutions with incomplete and imperfect experimental result are credible or not by a person skilled in the art.

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?

The perspective of a person skilled in the art is conducive to a unification with judgment criteria on the inventive step and is conductive to examination in practical work, because the examiners cannot have knowledge of an expert.

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

No

Please Explain

Such a requirement should be made only for the technical solutions of claims.

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

Inventions that have not been experimentally (fully or partially) verified for their effects or uses should not be patentable, as this would lead to spread unchecked of "enclosure-based applications" and patents, which would not be conducive to encouraging enterprises or individuals who are genuinely engaged in diligent research and development.

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 basis of speculation: potential experiments to preliminarily verify their effects and uses, such as compound interactions at molecular level, morphological or phenotypic changes at cell model level.

The process of speculation: based on these experimental results, the person skilled in the art can confirm that the compounds are able to achieve alleged effects or uses based on common knowledge, or a plural of, for example 3, prior art documents from different authors in authoritative journals.

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?

If the technical solution with the effect is sought to be protected, its plausibility should be recognized. Because the effect of the technology can be foreseen based on the prior art, the plausibility of the effect of the technology will not be hampered even if the description is not further explained.

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?**

No

Please Explain

After this prohibition, all patentable patent applications are limited to those technical solutions which technical effects can be directly verified by experimental results. Inventions that have preliminary experimental results in the field of biology and chemical medicine with long R&D cycles cannot be protected, nor do they conform to the objective laws of scientific research. For example, compounds that are effective at the cellular or animal model level can actually be clinically effective. The possibility to be clinically effective of those kinds of compounds is much higher than that of the other compounds.

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

In practice, it is suggested to adopt the criterion of presumptive truth. Considering administrative efficiency and the principle of good faith, the examining authorities and the public should presume that the embodiments given in the application documents are true, not predictable. Based on this, if either party has sufficient evidence to the contrary to prove that an embodiment cannot be realized in practice, the applicant should bear the corresponding adverse consequences, such as restricting equivalence, narrowing the scope of protection, or even invalidating the patent, etc.

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

For example, it is not necessary in the case that some embodiments of the invention may deal with the plausibility but are not claimed in a claim.

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?**

It should be the application date (or priority date if any), because the predictive part of the application is also based on the prior art on the application date (priority date if any) and the level of the person in the art.

If it is plausible on the application date (or priority date if any) but proven wrong later, the corresponding granted claims in this part are not enforceable and should be declared invalid without affecting the public interest.

If it is not plausible on the application date (or priority date if any), but later proved to be correct, it cannot prove that the speculation of plausibility is correct on the application date (or priority date if any), but it is likely that it is found to be correct by further verification later.

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

Pure products/compounds are new in themselves, and their plausibility can be recognized as long as they have certain uses or effects, while the functional features and uses in product claims should make the person in the art more credible of their clearly defined functions and uses, that is, more experiments or more reasonable reasoning are needed to determine their plausibility.

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

The burden of proof with plausibility on patent application should be borne by the applicant, while the burden of proof without plausibility should be borne by the patent office/objector.

If the patent office/dissenter cannot prove the lack of plausibility, it should recognize the 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.**

Examination on plausibility will increase the difficulty and prolong the examination pendency. The impact should be considered comprehensively.

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

Pharmaceutical and chemical industries.