

Post-filing Data Submission in Chemistry Art: Insights and Tips

In chemical field, the technical effect of a claimed invention can only be verified by experimental data. In patent examination, to traverse a lack-of-inventiveness rejection, applicants could submit supplementary experimental data to show unexpected technical effects. With respect to this submission, practice varies. On one side, USPTO and EPO examiners are relatively flexible for applicants to present post-filing evidence (such as comparative data of unexpected results) to illustrate claimed inventions and weigh in favor of inventiveness. On the other side, SIPO holds a strict rule on acceptance and consideration of supplementary experimental data submitted by applicants.

Before 2017, according to the examination practice of China, if applicants wanted to submit supplementary experimental data to prove unexpected technical effects, experimental data, from which the technical effects can be obtained by a person skilled in the art, must be recorded in the application documents as filed.

In 2017, SIPO revised its guidelines on supplementary experimental data. The revised Guidelines for Patent Examination (effective April 1, 2017) expressly stipulate that: “[w]ith respect to experimental data submitted after filing date, the Examiner shall make an examination. The technical effects to be proved by the supplementary experimental data shall be obtained by a person skilled in the art from the disclosure of the application document” (Chapter 10, Part II).¹

To elaborate, SIPO explained: “[d]efining that the Examiner shall make an examination on the experimental data supplemented by applicants. Clarifying the misunderstanding ‘the supplementary experimental data is not considered’ that may be brought by the relative expression”.² According to the explanation, the revised Guidelines are only for clarifying a misunderstanding that the supplementary experimental data is not considered. SIPO is silent on whether the examination criteria on supplementary experimental data have been changed or not.

Whether the examination criteria on supplementary experimental data by SIPO are changed or not? The SIPO’s attitude is visible from the following invalidation case.

I. The Case before the Board

Case No. 4W105696. Jinliang Dai requested the invalidation of invention patent No. ZL201110029600.7 (Patentee: Novartis). Invalidation Decision No. 34432. Decision Date: December 27, 2017.

This case is one of the ten major cases of the Patent Reexamination Broad (the Board) in 2017, where in the examination criteria on supplementary experimental data were provided.

The Arguments from Both Parties

The patent in dispute relates to a pharmaceutical composition comprising a combination of Valsartan and Sacubitril for treating vascular diseases such as hypertension. In its specification, paragraphs [0047]-[0063] literally provide a specific experimental method and subsequently conclude that the claimed combination has a synergistic effect without any specific experimental data to verify this effect.

Petitioner of the invalidation argued: the closest prior art has disclosed a composition of NEP inhibitor and Angiotensin II antagonist for treating hypertension. Meanwhile, there is evidence to show that Sacubitril is a known NEP inhibitor, and Sacubitril is a known Angiotensin II antagonist, both of which have the effect of lowering blood pressure. The patent claimed that the pharmaceutical combination has synergistic effect, but this effect was not verified. Therefore,

¹ Although this is stipulated in the section of sufficient disclosure, the experimental data for proving the unexpected technical effects should meet the requirement on sufficient disclosure in examination practice of China.

² <http://www.sipo.gov.cn/zscqgz/1100710.htm>

claim 1 does not possess inventiveness.

In response, the patentee submitted supplementary experimental data in the invalidation procedure to prove the unexpected technical effects of the combination of Valsartan and Sacubitril in lowering blood pressure.

Therefore, the key to judge the inventiveness of the patent is whether the supplementary experimental data can be accepted. In other words, it is the key that whether a person skilled in the art can obtain the unexpected technical effects of the pharmaceutical combination from the literal recitation of the patent documents.

The Viewpoint from the Board

The viewpoint of the Board is as follows.

A pharmaceutical combination is a known principle for selecting anti-hypertensive drugs. According to the full understanding of common knowledge evidence, the pharmaceutical combination with synergistic effect is selective rather than arbitrary. While a pharmaceutical combination might obtain a synergistic effect for treating hypertension, the patent only provides a summarized description for the pharmaceutical combinations which have been verified for synergistic effects, rather than universal law. Therefore, a person skilled in the art would not be able to conclude that a combination of any different anti-hypertensive drugs can obtain a synergistic effect.

As for this case, based on common knowledge in the art, a person skilled in the art could not conclude that the combination of Valsartan and Sacubitril has synergistic effect in lowering blood pressure. Therefore, this synergistic effect should be verified by efficacy experiment.

Efficacy experiment involves experimental method, experimental data and result, conclusion and the like. The experimental method is easy to obtain. The experimental data and result are critical to prove the effect of the drugs. The conclusion is established on the statistical analysis of the experimental data. Paragraphs [0047]-[0063] of this patent disclosed the experimental method involving animal model, dosing method, daily dose, and testing index. "The available results indicate an unexpected

therapeutic effect of a combination according to the invention" disclosed in Paragraph 0063 belongs to experimental conclusion. However, the description fails to disclose any specific experimental data or result. Under the circumstance that a person skilled in the art cannot predict the synergistic effect of the combination, the experimental conclusion without verifying by the experimental data and result cannot make a person skilled in the art determine the synergistic effect of the drugs.

Therefore, the technical effect proved by supplementary experimental data does not belong to the technical effects which can be obtained from the initial description by a person skilled in the art, and thus the supplementary experimental data cannot be accepted.

II. Insights

From above case, it can be seen that regarding the technical effects without verifying by experimental data, the examination criteria of the Board are:

1. With respect to expected technical effects, even no experimental data is provided in the application document, the technical effects could be obtained by a person skilled in the art by means of common knowledge in the art. For example, Valsartan and Sacubitril are known compounds for lowering blood pressure. After combining them, if no counterevidence is present, a person skilled in the art would expect a certain effect of lowering blood pressure of the combination, even if no experimental data is provided in the description.

2. With respect to unexpected technical effects, since the unexpected technical effects do not belong to the technical effects that could be obtained by a person skilled in the art by means of common knowledge in the art, if no data is provided to verify these effects in the application document, a person skilled in the art could not obtain these effects from the disclosure of the application document, even if there are literal recitations of these effects in the disclosure.

From above case, the examination criteria on supplementary experimental data by SIPO are not substantially changed.

III. Opinions from Courts

In addition, the Supreme People's Court issued "Regulations on certain issues concerning hearing administrative cases of patent authorization and right verification (I) (draft)" on June 1, 2018 for public opinions.

Its Article 13 stipulates:

"When the patent applicant or the patentee of a chemical invention submits experimental data after the filing date to further prove that the technical effects provided in the description are sufficiently disclosed, and the technical effects could be determined by a person skilled in the art from the description, drawings and common knowledge in the art on the filing date, a people's court generally shall make an examination.

When the patent applicant or the patentee of a chemical invention submits experimental data after the filing date to prove that the patent application or patent has different technical effects with those of Reference, and the technical effects could be obtained directly and undoubtedly from the disclosure of application

document by a person skilled in the art on the filing date, a people's court generally shall make an examination."

It can be seen that the provision to accept supplementary experimental data by the court also is that the technical effect can be obtained directly and undoubtedly from the disclosure of application document.

However, since these regulations are still in seeking public opinions, we will report later once they are finalized.

IV. Our recommendations

Regardless of the examination criteria on supplementary experimental data, currently when an applicant drafts an application document in chemical field, conservatively, the experimental data should be recorded in the specification, for meeting the requirement of sufficient disclosure or for verifying the unexpected technical effects.

The newsletter is not intended to constitute legal advice. Special legal advice should be taken before acting on any of the topics addressed here.

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