

Examination of supplementary experimental data in patent authorization and confirmation procedures

Times : 2021.04.13

Experimental Data in Pharmaceutical Patents

Article 26.3 :

- 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.
- The following situations are considered unrealizable due to the lack of technical means to solve technical problems: "(5) The specific technical scheme is given in the specification, but no experimental evidence is given, and the scheme must be confirmed by the experimental results to be established."

Article 22.3 :

- Identification of "technical problems" in inventiveness judgment: determine the technical problems actually solved by the invention based on the technical effects achieved by the distinguishing features of the invention and the closest existing technology;
- Unexpected technical effects: If the invention has unexpected technical effects compared with the prior art, there is no need to doubt whether the technical solution has outstanding substantive features, and the invention can be determined to be inventive.

Changes of supplementary experimental data review standard

Guidelines for patent examination (2010) :

- ‘To determine whether the specification is fully disclosed, the content recorded in the original specification and claims shall prevail. Examples and experimental data supplemented after the application date will not be considered.’

Guidelines for patent examination (2017) :

- ‘The examiner shall examine the experimental data supplemented after the application date. The technical effects proved by the supplementary experimental data should be understood by those skilled in the relevant technical field from the disclosure of the patent application.’

In practice, there are different understandings of the technical effects that can be obtained from the contents disclosed in the patent application. One understanding is that as long as there is a written record in the specification; the other is that the technical effect must be confirmed by experimental data in the specification.

Changes of supplementary experimental data review standard

Guidelines for patent examination (2020) :

- “The examiner shall review the experimental data that the applicant has to submit after the application date in order to meet the requirements of Article 22.3, Article 26.3, of the Patent Law. The technical effects proved by the additional submission of experimental data should be understood by those skilled from the disclosure of the patent application.”

Changes of supplementary experimental data review standard

Patent Examination Guidelines (2020) :

- Example 1
- Compound A is claimed, and the specification describes the preparation example of compound A, the blood pressure lowering effect and the experimental method for measuring the blood pressure lowering activity, but the experimental result data is not recorded. In order to prove that the invention is fully disclosed, the applicant submitted supplemental data showing the blood pressure lowering effect of compound A.
- Those skilled in the art understood that the blood pressure-lowering effect of Compound A was disclosed in the original application, and the technical effect proven by the supplementary experimental data could be obtained by following the disclosure of the original patent application.

Changes of supplementary experimental data review standard

Patent Examination Guidelines (2020) :

- Example 2
- Compound of general formula I is claimed. The specification describes the general formula I and its preparation method, the examples of preparation of a number of specific compounds A, B, etc. in the general formula I, the anti-tumor effect of compounds of general formula I, experimental methods for determining anti-tumor activity, and data on the experimental results. The experimental result data is disclosed as the IC50 value of the compound of the example on tumor cells is in the range of 10-100 nM.
- In order to prove the inventiveness of the claims, the applicant submitted comparative experimental data, which showed that the IC50 value of compound A was 15nM, while the compound of Comparative Document 1 was 87nM.
- Those skilled in the art understood that compound A and its anti-tumor effects were disclosed in the original application, and the technical effects proven by the supplementary experimental data could be obtained based on the disclosure of the original patent application.

Changes of supplementary experimental data review standard

CNIPA (China National Intellectual Property Administration) No. 47087 Invalidation Decision (2021) :

- For technical effects that are recorded in the specification but without specific experimental data, if the person skilled in the art, considering the specification as a whole, is sure that the patentee understood the technical effect and conducted research on the technical effect before the application date, and the effect can be obtained based on the content disclosed in the specification, then, if the patentee needs to supplement the corresponding experimental evidence after the filing date to meet the examination requirements, the experimental evidence can be taken into consideration as a basis for proving the technical effects of the invention.

Changes of supplementary experimental data review standard

<Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Administrative Cases Concerning Patent Grant and Confirmation (1)>(2020) :

- Article 10 If a pharmaceutical patent applicant submits supplementary experimental data after the filing date, and claims to rely on the data to prove that the patent application complies with the provisions of Article 22.3, Article 26.3 of the Patent Law, the court shall examine it.

(2019) Administrative judgment No.33 of Supreme Court :

- Because of inconsistencies in how those skilled in the art understand the prior art, the technical solutions of the invention, and the level of the state of the art, it is inevitable that the applicant would not record complete, specific experimental data in the original application documents sufficient to satisfy everyone. Therefore, the supplementary experimental data submitted by the patent applicant after the filing date should be examined.
- However, allowing patent applicants to submit supplementary experimental data and that it should be reviewed does not require that the supplementary experimental data be accepted.

Changes of supplementary experimental data review standard

(2019) Administrative judgment No.33 of Supreme Court :

- The conditions for accepting supplementary experimental data are as follows:
- (1) The original patent application documents should clearly record or implicitly disclose the facts to be verified that the supplementary experimental data intends to directly prove; if the facts to be directly verified by the supplementary experimental data are clearly recorded or implicitly disclosed by the original patent application documents, it can be determined that the applicant has completed the relevant research, and the acceptance of the supplementary experimental data does not violate the principle of first application;
- (2) The applicant cannot make up for the inherent defects of the original patent application document through the supplementary experimental data. Supplementary experimental data usually should prove the accuracy of the statements that are clearly recorded or implicitly disclosed in the original patent application, so as to supplement the legal requirements and facts that the applicant or the patentee will ultimately prove, rather than independently prove undisclosed contents of the original patent application in order to overcome inherent defects such as insufficient disclosure of the original patent application.

(2019) Supreme Law Zhixingzhong No. 33 Administrative Judgment 志霖律师事务所 ZHILIN LAW FIRM

- Paragraph 0005 of the "Background Technology" section of this patent specification states that "the compound exhibits high efficacy as a P2T receptor (P2YADP or P2TAC) antagonist. It also has surprisingly high metabolic stability and bioavailability". However, the other parts of the specification did not mention the above technical effects, nor provided experimental data to prove that the above technical effects did exist.
- Court of first instance: Because the above technical effects are only recorded in the "Background Technology" part of the specification, but are not mentioned again in other parts of the specification, and no experimental data are provided, those skilled in the art cannot confirm that this patent has the above technical effects. This is based on the prior art, the facts that the supplementary experimental data (proof 5) provided by the right holder was generated after the filing date, the proof 5 is an experiment conducted by witnesses who have an interest in the patent holder, and there is no other evidence to support the patent. Thus the technical problems actually solved in this patent cannot be supported by the technical effect contained in the proof 5.
- Supreme Court: In this case, the original patent application document recorded the technical effect of "surprisingly high metabolic stability and bioavailability". However, those skilled in the art cannot determine whether the compound of claim 1 actually has this effect based on the original patent application documents. The supplementary experimental data provided by the patentee intends to prove the accuracy of the statements, that is, the compound of claim 1 does have "surprisingly high metabolic stability and bioavailability," in order to supplement the legal requirement that claim 1 is inventive, so the supplementary experimental data should be accepted.

THANKS

志霖律师事务所

Add: 北京东城区北三环东路36号环球贸易中心C座2001-2007

Tel: 010-6409 7197

Fax: 010-8400 4936

www.zhilinlaw.com

北京、重庆、天津、海口、苏州、梅州、潍坊

Beijing, Chongqing, Tianjin, Haikou, Suzhou, Meizhou, Weifang