Theoretical and Practical Study on Experimental Evidence in Patent Administrative Procedures

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I. Background and Issues

The main characteristic of experimental science lies in its poor predictability which leads to a reliance on experimentation. And experimental evidence, which functions to consolidate the process and results of an experiment in the form of evidence, is indispensable in the assessment of patentability of inventions in the fields of experimental science such as chemistry, pharmacy, biology and materials.

As noted by the United States Court of Appeals for the Federal Circuit (CAFC), "although the content varies, the threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility." [1] In order to prove that an invention has been completed at the time of filing the patent application for the invention, instead of still at the stage of theory or research plan, and to support that the invention possesses inventive step for achieving certain technical effect over the prior art, where the technical effect, regardless of being literally recited in the patent description or asserted by the applicant (or the patentee) subsequent to the filing of the patent application, cannot be foreseen by those skilled in the art, experimental evidence needs to be called in to confirm the establishment of the technical effect. [2]

In respect of experimental evidence, on the one hand it has always been an issue of concern within the intellectual property industry, to such an extent as illustrated by the fact that contents such as "China affirms that the Chinese Patent Examination Guidelines permit patent applicants to file additional data after filing their patent applications" have been written into the Joint Fact Sheet between the U.S. and China. [3] On the other hand, the deficiency in relevant examination principles and norms has rendered experimental evidence a tough, hot issue specific to the fields. From the cases involving examination of experimental evidence, we can tell beyond any doubt by their sheer number the extensive use of experimental evidence, and at the same time the intractability and controversy of its examination criteria.

II. Current norms, practice and problems

By review of prevailing examination practice, we find the following two typical improper manners of dealing with experimental evidence: 1. In some cases, the closing-the-door approach is adopted, where post-filing experimental evidence is not considered or accepted for examination, often on the grounds that "experimental data submitted by applicants are not recited in the description"; because of such rejective attitude toward post-filing experimental evidence, there arises the formal requirement that experimental evidence must be recited in the description, as to the examination under Article 26.3 as well as Article 22.3 of the Chinese Patent Law; 2. Hasty acceptance of new effects found by the applicant after the filing date, among them even some technical effects eventually proved to be fictitious, which results in a certain number of granted patents for invention in such fields being declared invalid after grant.

An overview of the Chinese Guidelines for Patent Examination ("the "Guidelines") finds that the Guidelines as the comprehensive examination standards for guidance of patent examination practice contain some confusions and blind spots that need to be deliberated and addressed. To start with, the Guidelines provide a number of ways of dealing with experimental evidence (especially post-filing exper-

imental evidence), such as "shall not be taken into consideration", "shall be taken into consideration", "reference may be made" and "shall not be accepted". What exactly do these expressions mean? After that we need to address such issues as "when to take into consideration", "how to take into consideration", "when to make reference", "how to make reference", and "when to accept". Since examination of experimental evidence may in fact be associated with examination under various legal provisions related to the grant of patent, what we need to resolve ultimately is the relationship between the examination of experimental evidence and that of a series of specific legal provisions, which, in other words, is an issue of reasoning of examination on experimental evidence under respective legal provision.

III. Legal positioning of experimental evidence

"Evidence is the basis of justice: exclude evidence, you exclude justice." [4] Just because of the vital role of experimental evidence in drafting and examination of patent applications for invention (especially in the field of chemistry), the writers would start the discussion of issues related to examination of experimental evidence with the legal attributes of experimental evidence.

In applying conceptual thinking to the discussion, clarifying the denotation and connotation of a concept is required. The concept of "experimental evidence" has its origin in the Guidelines. Although "experimental evidence" has not been defined in any patent-related legislative documents, we can at least infer from its name that experimental evidence is a type of evidence, and contend that specifying the concept of experimental evidence as the connotation of evidence is the prerequisite for application of regulatory and normative legal thinking. Hence, examination on experimental evidence is before anything else a matter of examination on evidence.

Evidence is the factual material in support of the objective existence of an object or the truth of an assertion, and "evidence is the unification of the contents of an objective fact and its form of manifestation". [5] It is embodied as "the unification of the contents (factual materials) and form (means of proof) of evidence" [6]. As far as patent administrative procedures are concerned, experimental evidence should first of all exist in a certain form (e.g. attached to a carrier of evidence as written report or video material), and is the foundation for those skilled in the art, the fictitious figure contemplated by the examiner, to judge on the basis of relevant experiment (including the experimental results achieved) whether the fact to be proved, or *factum probanda*, in connection with the conditions for patent grant exists or not. And experimental data should be the primary technical information in experimental evidence. [7]

In past practice, there was a divergence in the manners of dealing with experimental evidence. One reason for such divergence is the separation of the attributes of experimental evidence from the contents thereof. In other words, people tend to pay more attention merely to experimental data, in particular the value of quantitative data, as recited in the experimental evidence, and indiscriminately accept the experimental results presented by the data and accordingly grant the patent, while ignoring the examination on the process leading to the experimental data and results as well as the relation between the experimental results and the technical contributions of the patent, thus resulting in the departure of the examination of experimental data from the reasoning of examination of evidence. Such indiscreet way of dealing with post-filing data may sometimes place the experimental data in the blind spot of public supervision, which incidentally offers an opportunity for exploitation by evidence forgers.

Similar to other cases, patent administrative granting and affirming proceedings need to adhere to facts as the prerequisite and foundation for application of laws. In all of the three major Chinese procedure laws, evidence is divided into types, for example, the Administrative Procedure Law of China classifies evidence into eight types, among them documentary evidence. [8] However, none of the said procedure laws have provided for experimental evidence as a specific type of evidence. The conceptual ambiguity between experimental evidence and similar evidences can lead to differences in the choice of specific examination criteria.

In light of the fact that experimental evidence primarily involves the experimental process and conclusion, expert opinion is the type of evidence closest to experimental evidence. Some court once referred to relevant requirements for expert opinion when evaluating the qualification of experimental evidence in a patent-related administrative case. The major similarities between experimental evidence and expert opinion lie in: they both are scientific evidence, draw-

ing experimental conclusions based on analysis of experimental data obtained in experiments using experimental means, scientific instruments and equipment etc., and the role of technical appraisal in patent invalidation proceedings is similar to that of expert testimony in civil proceedings as they both intend to prove the fact related to case trial at the technical level.

That being said, experimental evidence and expert opinion are still different concepts. Expert opinion is issued by an accredited institution or personnel, with relevant laws setting forth explicit requirements for the time of issuance, the form and the procedure thereof. And expert opinion may contain experimental process and data, whereas experimental process and data are not confined to the evidential form of expert opinion.

There is also a view that experimental evidence which is provided by a party concerned and not given by an accreditation agency may be addressed as "private appraisal" or regarded as the like of "expert witness evidence". Obviously, this type of expert opinion deviates further from the scope of expert opinion under the procedure laws. Thus, in the event where expert opinion involves experimental process and results, the expert opinion may be treated as a special type of experimental evidence, but the experimental evidence, however, cannot be treated as expert opinion.

Documentary evidence also shares some similarities with experimental evidence. "Documentary evidence" refers to documents or other objects that support the fact of a case by contents in the form of words, signs or graphs etc. [9] Experimental evidence also bases the proof of fact on the contents expressed in words, numbers, tables or drawings etc. However, documentary evidence by comparison is obviously characterised by greater stability and more definite contents.

It can be thus seen that experimental evidence by nature falls within the scope of evidence, and the principles of and rules for examination of evidence are also applicable to the examination of experimental evidence. Nevertheless, we may not oversimply apply the specific provisions and manners of dealing with evidence under conventional rules of evidence such as those dealing with documentary evidence and expert opinion. Instead, attention should be paid to the similarities and particularities of experimental evidence relative to documentary evidence and expert opinion. A due respect for the attributes of experimental evidence during the examination on grant and affirmation of patents can mainly be manifested in the following three ways:

1. Treat experimental evidence as evidence. Experimental evidence should be taken into consideration in the course of arriving at the conclusion of examination insofar as the filing of the experimental evidence complies with relevant procedural requirements, and should not be excluded from examination merely on the grounds that it is furnished or published subsequent to the filing date of the patent application. As to whether the evidence can support the assertion of a party, it should be left to comprehensive analysis based on the competency and probative value of evidence under the principles of patent examination.

2. Keep the examination on experimental evidence in line with the general reasoning of examination on evidence. First, consider whether the experimental evidence possesses competency (i.e. admissibility, also known as qualification of evidence within the industry), that is to say, whether experimental evidence is authentic (objective), legitimate and relevant, and on this basis evaluate the probative value of the experimental evidence. Then combine said evidence with other evidences to form the chain of evidence for judging whether the asserted *factum probanda* can be confirmed.

3. In dealing with specific issues related to examination of evidence, follow relevant provisions of laws, regulations and the Guidelines in the first place. As for the circumstances not specified in the Guidelines, reference can be made to the existing rules of evidence in legal proceedings (e.g. rules of evidence in civil proceedings) with respect to examination on similar type of evidence.

Even in part of the patent-related administrative procedures where written examination dominates, we should still address the issues related to experimental evidence with the same attitude and manner as we adopt in dealing with evidence. However, in consideration of the characteristics of each specific procedure and the system cohesion between various procedures, the specific contents of the examination on experimental evidence should reflect appropriate differentiation and emphasis to accommodate different examination procedures. For instance, in respect of an embodiment in the description, as documentary examination is undertaken during the stage of substantive examination, the experimental result of the embodiment is to be presumed as authentic and objective where no obvious de-

fects are found; however, in the examination during invalidation proceedings, if a requestor is able to raise reasonable doubt or provide valid evidence to prove that an experimental process or result of the embodiment is erroneous, for example, entirely different experimental result is found upon entrusting a qualified experimental institution to repeat the experimental process recited in the embodiment, the evidence can be overturned, and it can be concluded that the fact to be proved by the party based on the evidence does not exist.

IV. Examination on experimental evidence

(I) Competency of experimental evidence

"Competency of evidence", also known as qualification of evidence or admissibility of evidence, refers to the properties which the evidence should possess when used as the basis of a decision in a case. It represents the ability of evidential materials in functioning as evidence. Evidence competency generally refers to three properties of evidence, namely, authenticity (objectivity), legitimacy, and relevancy.

1. Authenticity of experimental evidence

By "authenticity of evidence", it means that the form and contents of evidence should be true and objectively existing. As compared with other evidence, experimental evidence is more complicated when it comes to judgment on authenticity and probative value, which is attributive to its own particularities.

The particularities of experimental evidence are mainly shown in the following aspects: first, various elements of the experimental process (including experimental materials, steps and conditions, and even the experimenters) can directly affect the experimental results, for example, experimental results and analytic processing thereof may be affected by the experimenters and report writers' experimental skills, their analytical, comprehension and computational capabilities, or even subjective factors of them. Secondly, verification of the experimental results provided by the experimental evidence is a tough job, as it is usually hard to infer the results from other evidence or theories, and cross-examination and expert witnesses can play only a very limited role in the examination process. The experimental results can be validated only by means of experiments, unless the results can be overturned straightly because of some obvious defects of the evidence *per se*. Moreover, only on the premise that the whole process of experiment is clearly, specifically, and fully recorded can the experimental evidence be validated and verified by means of experiments, otherwise it is usually hard to verify the authenticity of experimental results by way of reproduction. And thirdly, while authenticity and objectivity in examination of ordinary evidences tend to merely relate to preference of wordings, the objectivity of experimental results will affect the admissibility of experimental evidence. Notwithstanding that in some cases the experiment has been truly conducted and the results thereof are observed and faithfully recorded by experimenters, objectivity of the experimental results may be affected by the experimental standard as well as accuracy and appropriateness in the operation of the experiment. [10]

Hence, the examination of authenticity and probative value of experimental evidence need to take into account the following aspects in accordance with the actual situations: ① manner of submission of the experimental evidence, for example, whether in original or notarised copy, and whether the photocopy or duplicate corresponds to the original; ② source of experimental evidence, such as why and how the experimental evidence is formed, and the objective environment for obtaining the experimental evidence; ③ whether the experimental evidence is originally acquired or has undergone statistical processing; ④ whether the provider and completer of the experiment have any conflict of interest with a party concerned so that the authenticity and objectivity of the experiment are likely to be affected (in practice the influence of conflict of interests is seen more on the probative value of the experimental evidence); ⑤ whether the experimental evidence has serious defects (e.g. whether the experimental process is described clearly, specifically and fully, and whether the experimental design and operations have obvious errors); ⑥ qualification of the provider and completer of the experimental evidence; ⑦ the testimony of the witness at court (attention should also be paid to the identity of the witness and whether the witness is testifying for the experimental process he has personally experienced); and ⑧ other factors that may affect the authenticity of evidence.

Authenticity of evidence encompasses authenticity in form and in contents. Evidence for proving the fact of a case should be authentic at least in form. Falsified or forged evidence is inadmissible. The experimental evidence should provide clear and detailed description of the experi-

mental process to the greatest extent so that those skilled in the art can reproduce the experiment accordingly in order to confirm the authenticity of the experimental results. While it is unable to impose a uniform requirement regarding what makes a detailed description of the experimental process, it is understandable that where the description of the experimental process misses or falsifies any key methods, steps or conditions that may influence the experimental results, or where the experimental process involves unreasonable operations which obviously defy common knowledge of the art, the experimental results will be rendered untrustworthy. It shows from some actual cases that it is not uncommon for a party, where his vital interests are implicated, to be motivated and driven to provide forged experimental evidence to confuse and interfere with the accurate affirmation of the fact.

Take for example a patent directed to a method for preparing a compound. The description of the application for the patent recited the results of a map test of the product derived from the method to prove that the method was capable of preparing the target product. However, another method for preparing the same compound as mentioned, along with the map derived from a test of the product prepared by that method, was recited in Exhibit 1 submitted by the requestor during the invalidation proceedings. The requestor asserted that the map as appeared in the patent in suit did not result from the method of the patent, and the fact that the patent in suit and Exhibit 1 had identical product test maps despite adopting different methods was a result of the embezzlement of the test map of the product prepared by the method of Exhibit 1. The collegial panel, after analysing the preparing methods of the patent in suit and Exhibit 1, comparing the maps of the two, and referring to the prior art in combination with experimental knowledge of the art, affirmed that the map test results recited in the patent in suit were the experimental results of the product of Exhibit 1 with no direct relevance to the method of the patent in suit, and hence could not be used to prove that the method of the patent in suit could attain the target product.

In another example, the patentee in a patent invalidation case involving a chemical product invention submitted a counter-evidence 13, which was the written testimony produced by a research personnel in which the process for preparing the chemical product was recited. The witness stated that the reactor used in the preparing process was a 250ml three-necked flask equipped with a mechanical stirrer. However, even if the volume of solid materials added to the flask was excluded, the volume of the added liquid alone already amounted to 312ml, which was far beyond the nominal volume of the reactor. Furthermore, the reaction was required to be carried out at a temperature higher than 50℃, and following the increase of temperature the volume of the solution would expand. Notwithstanding this, the witness still alleged an addition of 15g solid materials, to be stirred at an elevated temperature by a mechanical stirring device. In such a case, the solution would certainly overflow, which was not allowed in practice. Since such contents defy common sense, the evidence was not accepted by the collegial panel.

In a further example, a pesticide enterprise and a university jointly developed an agricultural compound and filed an application for patent on the compound. Afterwards, the enterprise, when conducting researches on the combined use of the compound and a known pesticide, found that a competing company had filed massive patent applications for the combined uses of the compound and all known pesticides that could be applied to the combined uses, and that the applications were based on apparently untrue and contradictory experimental data. The competing company even made a bold proposal to the enterprise for being granted a license for the prior patent on said agricultural compound, claiming that it would be difficult to have the defects of the experimental data in those combined medicament patents confirmed one by one via invalidation proceedings.

In light of the above, we should try our best to render the experimental evidence free from formal defects at the time of filing. At least the information in the experimental evidence, from operating method to experimental results, should be clear and detailed so as to ensure that the public can verify the objective authenticity of the experimental results accordingly. In addition, we should at least provide the names of the natural person and the institution who complete the experiment so as to facilitate further verification of the experiment in subsequent procedures. These views of the writers can find an echo in the European Patent Office's Boards of Appeal, which required, for example, that "any comparative test presented must be reproducible on the basis of the information thus provided, thereby rendering the results of such tests directly verifiable (T494/99)" and pointed out that "(v)ague and imprecise operating instructions render the test inappropriate and thus irrelevant (T172/90)."

Given that substantive examination of a patent application is conducted in written form, a pitfall for the parties concerned at this stage is, they may mingle narration with comments when stating the key experimental process and results in the observations. Such formally defective evidence can hardly defend itself against the attack of the requestor in patent affirmation or judicial procedures, and, even if the application is granted, may still become a potential threat to the stability of the patent. As to the examiner of evidence in written form who may not possess the experimental capability to verify the objective authenticity of the evidence, problem may arise if all his attention is directed to the value of experimental results without considering how the results are obtained. Therefore, it is necessary for the examiner to form in mind some systematic thinking in relation to the examination of evidence.

Additionally, whether in patent grant procedure during which written examination is dominant or in subsequent invalidation proceedings, notarisation and authentication should be duly handled. In view of the characteristics of experimental evidence, experimental evidence with its experimental process and results notarised or completed by an entrusted qualified authentication agency is more advantageous in terms of creditability than experimental evidence otherwise, though it still needs to undergo analysis and judgment in adherence to the normal reasoning and principles of examination on evidence, that is, notarisation and authentication should not take the place of examination on competency and probative effect of experimental evidence.

In brief, as regards the treatment of experimental evidence during the examination on patent grant and affirmation, we should consider not only the particularities of experimental evidence in terms of contents, form and formation process as well as its relation with the *factum probanda* specific to the patent law, but also the realisation of the evidential attributes of experimental evidence.

2. Legitimacy and relevance of experimental evidence

By "legitimacy of evidence", it means that the subject who provides evidence, the form of evidence, and the evidence collection procedure or extraction method must comply with relevant legal provisions, and evidence that is not provided or collected according to legal procedures generally cannot serve as the basis for affirmation of the fact of a case. Legitimacy of experimental evidence is examined mainly in terms of following aspects: ① whether the experimental evidence is in legal form; ② whether the acquisition of experimental data complies with the requirements of laws, rules and regulations; ③ whether there is other violation of law that may affect the validity of evidence; and ④ why and how the evidence is formed.

As for "relevance of experimental evidence", it means that the fact used as evidence of a case should not be merely an objective reality, but must be logically connected to the fact to be ascertained in the case and is able to support the fact of the case, either alone or in combination with other facts. The fact used as evidence, if not connected to the fact to be ascertained, may not serve as evidence in support of the disputed fact even if it is true.

In practice, it is common to see the confusion between examination on relevance and probative effect. "Probative effect" reflects an opinion from the perspective of whether the *factum probanda* can be verified by means of the evidence, whereas "relevance", a factor of the qualification of evidence, considers the threshold of evidence, and emphasises the likelihood of association between the evidence and the fact of a case, that is, whether the evidence can be incorporated into the scope of consideration. Hence, the requirement on relevance is lower. The writers would like to borrow the interpretation on relevance in Rule 401 of the Federal Rules of Evidence of the US, which reads: "evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence and the fact is of consequence in determining the action". In general, evidence should be deemed relevant as long as the evidence submitted by a party has its purpose and object of proof relevant to the case. It is improper to examine the relevance of evidence with an eye toward the outcome of whether the asserted fact can be ultimately proved by the evidence.

(II) Probative value of experimental evidence

"Probative value" refers to the extent to which the evidence having evidence competency (meeting the requirements for qualification of evidence) tends to prove the *factum probanda* of a case. The examiner should conduct full and objective examination according to relevant legal procedure on the experimental data provided by a party, and make scientific, legal judgment based on such aspects as the extent of relevance of the evidences to the fact of the case and the connection between the evidences.

The purpose of proof of evidence is always connected to specific *factum probanda*. For experimental evidence, its purpose of proof is primarily directed to specific technical

effect. And as to whether the technical effect that a party intends to prove by the evidence falls within the scope of patent examination should be an issue to be examined under evidence competency or under probative value, there are different views and courses of action in practice. To illustrate the situation we would take as an example the requirement that the asserted technical effect should be based on the disclosure in the original application.

The first view holds that if the fact (technical effect) to be proved by the experimental evidence is not disclosed in the original application, the evidence should not be taken into consideration. Such simple conclusion of "should not be taken into consideration", however, is obviously in breach of our stance toward examination of evidence as advocated herein, and will also conceal the evidence evaluation process of the collegial panel. Moreover, the rigid expression of "should not be taken into consideration" can trigger ambiguous interpretation, thus resulting in discontent of the party who produces the evidence.

The second view is, if the fact (technical effect) to be proved by experimental evidence is not disclosed in the original application, the evidence has no probative value. This view holds that specific requirement (e.g. inventive step and sufficient disclosure) on technical effect in patent examination should be applied to the requirement on the qualification and probative value of experimental evidence. Furthermore, the view contends that experimental evidence should above all address the technical effect recited in the original application, and in the examination involving inventive step, experimental evidence should address the technical effect brought by the technical feature distinguishing the invention from the closest prior art. It is believed that only in this way can the evidence meet the qualification and probative value requirements; otherwise, even if the evidence has sufficient probative value to support the *factum probanda* (such as the existence of certain technical effect), it will still lead to the conclusion that the evidence has no probative value because the effect cannot be incorporated into the scope of examination on specific provision.

In the opinions of the writers, the first view should be ruled out. It is generally believed that where the evidence meets the requirements on the three properties of patentability, it will be more convincing to the parties concerned and at the same time helps strengthen the objectivity of the conclusion upon comprehensive analysis and comparison of various evidences if the establishment of *factum probanda* is included as an issue of probative value in the examination. As to the judgment of the qualification aspect such as authenticity and relevance of the evidence, we should not be too severe. With due allowance for defects in the qualification of evidence, we should take examination on probative value of evidence as a better safeguard in the pursuit of fairness of outcomes.

The second view is also not recommendable. In respect of what kind of technical effect to be acceptable during the examination on patentability, it is an issue decided by legal provisions related to patent grant, rather than the obligation of evidence examination. Some technical effect, even if it has been verified by evidence, is still not able to serve as the factual basis of meeting certain provision. This does not mean the evidence fails the qualification test, nor has it anything to do with the probative value of the evidence *per se*. In fact, sometimes the parties do not submit experimental evidence just for proving a single fact, for instance, not all evidence is for proving certain effect possessed by the invention as of the filing date, and whether the stated effect is acceptable may not always be that clear cut. Although this view, with a conclusion of no probative value, seems to have averted the "oversimplification and crudeness" of the first view, it still maintains in essence a stance of closing the door on the experimental evidence that fails the qualification test. In reality a case often mingles fact and evidence. And in some situations, if we "let pass" some evidence or refrain from jumping to conclusion during the examination on the qualification of evidence so that the evidence is incorporated into overall consideration in subsequent judgment, it may be more conducive to objectivity in the affirmation of fact and accuracy of law application.

Furthermore, it is the requirement under a first-to-file system that the technical effect of an invention obtained by those skilled in the art from reading the originally filed patent documents should serve as the factual basis for judgment of patentability. Thus, from the perspective of the one who makes the judgment, it is generally believed that only when the experimental evidence is directed to the technical effect of an invention disclosed in the original application can it be constructive to the acquisition of a patent. However, such requirement comes from the provisions relating to the conditions for patent grant under the patent law; it is not an obligation under examination on qualification and probative value of evidence. In principle, whether an application

is patentable and compliant with the requirement of certain provision is a different matter from the judgment on the probative value of evidence. It is hard to imagine that we can substitute the examination on qualification and probative value of evidence for that on patentability.

The judgment on probative value is directed merely to the *factum probanda* that a party intends to prove by the evidence. Where the *factum probanda* in the experimental evidence submitted by a party concerns a technical effect, the evidence that possesses sufficient probative value may support the *factum probanda*, i.e. the technical effect can be established. However, if the technical effect cannot be incorporated into the scope of patentability examination, for instance, the technical effect to be proved is not contributed by the invention as of the filing date, the technical effect cannot be used as the factual basis for the conclusion that the invention possesses inventive step. And the reason for such outcome has nothing to do with inadmissibility or poor probative value of the evidence.

(III) Standards of proof of experimental evidence

The nature of patent affirmation administrative proceedings closely resembles civil disputes resolution conducted by judicial organs, both of which are basically subject to the rules of evidence for civil proceedings, though the former should apply "high degree of likelihood" (also known as "probability") for administrative proceedings to the standards of proof, that is, the qualitative and quantitative objectiveness of evidence ultimately attained through the production and investigation of evidence and the debates between both parties, as well as the definiteness and clarity of the *factum probanda* reflected by such objectiveness. In other words, it is the attainment of conviction by the action of the objectiveness of evidence on the mental process of the collegial panel. Such standard of proof requires a higher probability. Although it does not necessarily require a degree of probability that reaches or approximates certainty, the fact cannot be ascertained merely by a low preponderance of evidence.

A patent is a property right granted by a patent administrative department under the State Council of China after going through an examination process. The grant or invalidation of a patent should be handled with extreme care, considering the importance of the stability of the patent right and the steadiness of social and legal relations, and based on the respect for the principle that administrative agencies' beneficial administrative acts should meet the legitimate expectation of the public and the society as a whole. Hence, a party who intends to prove an asserted fact by experimental evidence must have the evidence reaching a certain degree of proof before his assertion can be established and the fact used as the basis of law application.

V. Issues related to post-filing experimental evidence

It is generally believed that examination of experimental evidence submitted after the filing date is a tricky issue. Following the aforementioned reasoning of examination on experimental evidence, subsequent filing of experimental evidence itself does not mean that the evidence lacks the qualification of evidence or probative value. The key to resolving the issue of post-filing experimental evidence lies in knowing the difference between the post-filing experimental evidence and the experimental evidence recited in the original application documents.

Seemingly, post-filing experimental evidence is in a disadvantageous position in countries adopting the first-to-file system, because of its being dated after the filing date and on account of its not being recited in the description. In a first-to-file country, the filing date of a patent has significant meaning, and the application documents as of the filing date are primarily important legal documents, with the recitation in the description of the invention-creation implemented and completed by an inventor being the basis for deciding whether an application will be granted and if so, what kind of right to be granted. As such, the experimental evidence recited in the description will naturally be treated as part of the work contributive to the inventive work completed by the inventor as of the filing date. Hence, the admissibility of post-filing experimental evidence hinges on under what circumstances will the contribution proved by the post-filing experimental evidence be deemed as part of the contribution made by the applicant by the filing date.

The filing date is the time point to define not only the scope of prior art, but also the completion and contribution of an invention. Patent examination requires the examiner to weigh the work and contribution by the applicant as of the filing date on the basis of the prior art from the perspective of those skilled in the art. It means that, although this article commends that the examiner takes into consideration all the post-filing experimental evidence submitted by the ap-

plicant, if the applicant intends to change by means of the post-filing experimental evidence the fact as of the filing date as determined by both the application documents filed on the filing date and the prior art, the assertion of the applicant will not be accepted.

Owing to the above reasons, many countries have specified in their examination standards and judicial judgments that the technical effect of an invention to be proved by the post-filing experimental evidence should be supported by the original application documents. In China's latest revised Guidelines for Patent Examination, it is provided that "the technical effect to be proved by the supplementary experimental data shall be one that can be obtained by those skilled in the art from the contents disclosed in the patent application", implying that the provision also underscores the importance of the filing date as the time point to define not only the scope of prior art, but also the completion and contribution of an invention. Accordingly, if the applicant wants to prove by means of post-filing experimental evidence that an invention has attained certain technical effect, such experimental evidence must be directed only to the technical effect that can be obtained by those skilled in the art from the contents disclosed in the patent application.

In respect of the judgment that the technical effect "can be obtained from the contents disclosed in the patent application", the above-mentioned revised Chinese examination guidelines emphasise the requirement that the examiner or other assessors should base their judgment on the disclosure in the original application documents from the standpoint of those skilled in the art. For this reason, the judgment is made on the basis of the skilled persons' perception of the contents recited in the documents under examination. For instance, where the information from the prior art as cited in the application documents acts on the understanding of the patent application, the affirmation of the disclosed contents by those skilled in the art will be affected accordingly. Moreover, those skilled in the art will apply their mastery of the ordinary technical skill to achieve a thorough understanding by digestion and assimilation, or additionally by analysis and inference, of the contents literally recited in the patent in context, rather than simply check whether the contents are literally recited or what kind of data are provided in the description, thereby avoiding dogmatic and mechanical judgment in practice.

As regards the technical effect that can be obtained by those skilled in the art from the contents disclosed in the patent application, it usually refers to the technical effect of an invention that can be affirmed by those skilled in the art based on the contents of the original application documents and the prior art. Any technical effect that is not recited in the original application documents and cannot be obtained by those skilled in the art from the contents disclosed in the patent application and the prior art does not belong to the technical contribution made by the applicant as of the filing date and cannot serve as the factual basis for ascertaining the technical problem to be practically solved by the invention.

Reexamination decision No. 12206 relates to the invalidation of a patent that claims a crystalline monohydrate of tiotropium bromide and a method of producing the same along with pharmaceutical compositions thereof. According to the description of the patent application, the object of the invention is to provide a new stable crystalline form of tiotropium bromide to meet the stringent requirements on pharmaceutically active substances, to obtain the monohydrate of tiotropium bromide in crystalline form by selecting specific reaction conditions, and to measure relevant data such as infrared spectroscopy and X-ray diffraction to characterise the crystals, though with no testing of other properties of the monohydrate. Subsequent to the filing date, the patentee submitted experimental data related to the tested particle size distribution and mean value of corresponding crystalline monohydrates in order to verify the technical effect of the invention that the crystalline monohydrate of the invention was capable of attaining particle size stability after micronising.

The invalidation decision deemed that: The invention merely had a general mention in the description of its object being related to stability and of the crystal morph and lattice associated with the manufacture of preparations. With no micronisation of tipetropium bromide monohydrate nor any recitation of the effect of particle size stability after micronising or any experimental data in that respect, those skilled in the art by reading the application documents could not get any teaching about the particle size stability achieved by the micronisation of the crystalline tiotropium bromide monohydrate based on the disclosure of the invention and the prior art, which meant that said effect could not be derived from the contents disclosed in the description.

Hence, for post-filing experimental evidence submitted by the applicant in respect of a technical effect which has been asserted in the original application documents, if

those skilled in the art, based on the technical information disclosed in the original application documents and the prior art, cannot affirm that the technical effect results from the invention, the technical effect, despite its being literally recited in the original application documents, cannot be deemed as the technical contribution made by the applicant as of the filing date regardless of whether the technical effect is verifiable by the post-filing experimental evidence.

Reexamination decision No. 69491 relates to a patent application which seeks protection of quinuclidine derivatives in the form of single enantiomers or mixtures thereof. The quinuclidine derivatives mentioned in the description of the application have adequate selectivity for the muscarinic M3-receptor and prolonged duration of action, and can be used for manufacturing drugs in the prevention or treatment of respiratory diseases such as asthma, chronic obstructive pulmonary diseases, coughing, and emphysema. The description, however, merely discloses the experimental result that the compound can reverse contractile responses caused by carbachol, but contains neither depiction of the activity and selectivity of the M3 receptor of the compound, nor any testing methods and conditions and any qualitative or quantitative experimental data resulting therefrom. Subsequent to the filing date, the applicant submitted experimental data containing the test values of corresponding compounds at muscarinic M2/M3 to support that the compound of the application had high selectivity for M3 receptors, but no testing methods and conditions were disclosed therein.

The reexamination decision deemed that: According to the disclosure in the description, carbachol was known in the art as a non-selective M receptor agonist capable of causing tracheal contraction. That the compound of the application was capable of reversing contractile responses to carbochol could just lead to the *prima facie* belief that the compound had an inhibitory effect on M receptors, but failed to enable those skilled in the art to determine therefrom that the compound had selectivity for M3 receptors as claimed. The description neither disclosed the experimental method of testing the selectivity of M3 receptors nor recited any relevant tests done for the claimed compound, including such experimental data as M2/M3 ratio of the compound, to confirm the high selectivity of the compound for M3 receptors. Since the selectivity of the claimed compound for M3 receptors could neither be determined from the disclosure in the patent application nor the prior art, the technical effect of high selectivity for M3 receptors intended to be verified by the applicant by means of the post-filing experimental data could not be derived from the disclosure in the original description.

In another type of patent applications, although the technical effect of the invention asserted by the applicant is presented after the filing date by way of post-filing experimental data, the original application documents have disclosed the technical effects of other technical solutions that are similar to the claimed technical solution, and if those skilled in the art by technical analysis and judgment can foresee on the basis of the technical effects of those similar technical solutions that the claimed technical solution generates the technical effect asserted by the applicant, the technical effect can serve as the factual basis for determining the technical problem to be practically solved by the claim.

Reexamination decision No. 74723 relates to benzamide compounds useful as histone deacetylase (HDAC) inhibitors. The description discloses that the compound is a potent inhibitor of HDAC and has been found to possess other favourable pharmaceutical properties, including advantageous cell or in vivo potency, advantageous DMPK properties, and good or enhanced solubility, and has further disclosed the data from in vitro assay relating to the inhibition of HDAC activity and of whole cell proliferation by the compound of Example 4. Subsequent to the filing date, the applicant filed the experimental data comparing the compound of claim 1 of the application and the contrast compound in the description; said data were obtained by the test methods recited in the description for proving that the benzamide compounds of the application had a potent inhibitory effect on HDAC.

The reexamination decision deemed that: According to the description, the technical solution of the application replaced pyridyl group in the prior art with an optionally substituted pyrazole group to which methyl piperidinyl group was attached so as to improve HDAC inhibitory activity. Both the compound of claim 1 and that of Example 4 were compounds cited in the examples of the description of the application. They were similar in structure, and distinguished from each other merely by the fact that the pyrazole group in Example 4 was further replaced by a methoxy group. Those skilled in the art, by means of structural analysis, could foresee that they produced similar technical effects with respect to HDAC inhibitory activity. That is to

say, in the absence of counter-evidence, those skilled in the art could expect similar HDAC inhibitory activity achieved by the compound of claim 1 based on the data related to the effect of the compound of Example 4 in the description. The post-filing experimental data validated the information derived by those skilled in the art from the disclosure in the description, and the inhibitory effect of the compound of claim 1 on HDAC as proved by the post-filing data was derivable from the disclosure in the original description.

VI. Conclusion

Where the applicant intends to prove by means of experimental evidence that a patent application meets the conditions for grant, the probative effect of the experimental evidence is generally dependent on the following two aspects: first, whether the technical effect which the applicant intends to verify by the experimental evidence can be validated; second, whether the technical effect can be obtained from the disclosure in the application documents by those skilled in the art. Only when both of these conditions are satisfied can the technical effect to be verified by the experimental evidence be established as the technical effect of the invention. And the said technical effect can then be taken as the factual basis for the assessment of patentability.

The reason why experimental evidence may serve as evidence lies in its function of clarifying facts. And experimental evidence, as the type of evidence most closely related to experimental science, is very often the most direct and convincing evidence for demonstrating a technical effect. Rather than confined to provisions related to inventive step, experimental evidence plays an important role in establishing the technical effect involving other provisions as well. Additionally, it can be used to dispel doubts raised by the examiner and refute arguments put forward by an opposing party. Some time ago the writers wrote an article on the relationship between experimental evidence and inventive step; however, for reasons of space, the article did not cover such aspects as qualification, probative value, and post-filing experimental evidence – a topic of much attention following the revision of the Guidelines. This piece of writing can be regarded as an attempt to complete our discussion on the issue according to the scope we have intended to cover. ■

The authors: Patent Reexamination Board of the State Intellectual Property Office

[1] *Ariad v. Eli Lilly* (CAFC 2009) (*en banc*).

[2] Li Yue (July, 2015). Experimental evidence and judgment on inventive step of patent. *China Patents & Trademarks*.

[3] Joint Fact Sheet on Strengthening U.S.-China Economic Relations, released on 5 December, 2013.

[4] Bentham. Rationale of judicial evidence (Part III, Chapter I).

[5] Fan Chongyi (editor-in-chief). Evidence law (2001 edition, pp. 45-46). Law Press.

[6] Bian Jianlin (editor-in-chief). Evidence law (2000 edition, p. 70). China University of Political Science & Law Press.

[7] Li Yue. Study on hot issues concerning experimental evidence. Study of Patent Law 2011.

[8] Article 33 of the Administrative Procedure Law, revised in November, 2014.

[9] He Jiahong & Liu Pinxin (2007). Evidence law (2nd edition, p. 157). Law Press.

[10] See supra note 2.