On the Determination of Post-Filing Experimental Data

Contents

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During the substantive examination and reexamination of an invention patent application as well as the invalidation proceeding after the grant of an invention patent, "lack of support by the description" (Article 26.4 of the Chinese Patent Law), "insufficiency of disclosure in the description" (Article 26.3 thereof), and "lack of inventive step over prior art" (Article 22.3 thereof) are defects commonly cited by the patent examiner, Collegiate Panel, or invalidation requester in China. And submission of supplementary experimental data (i.e. post-filing experimental data) is often relied upon by the patent applicant or patentee as a major means of overcoming the said defects, in particular where the invention concerns the fields of chemistry, pharmaceuticals, biology, or materials. Especially in contending against the lack of inventive step, the patent applicant or patentee would often leverage supplementary experimental data to prove the advantageous effect of an invention to thereby support the inventiveness of the invention.

Regarding the submission of supplementary experimental data as a means of proving inventive step in an invention, it is generally allowed by major patent offices of the world such as those of Europe, the US, Japan, and Korea. However, in China it has been a long-standing practice of the patent office to take a very strict examination standard toward supplementary experimental data, and these data are basically rejected by the examination authorities particularly when they are used for proving the advantageous effect of an invention. Notwithstanding the provisions in the revised Guidelines for Patent Examination (effective 1 April 2017) of **"[w]ith respect to experimental data submitted after the date of filing, they should be examined by the examiner", we cannot see any substantial difference in stance toward supplementary experimental data in examination practice to date (as of the end of 2017) since 1 April 2017 when the revised examination guidelines entered into force.**

This article focuses on introducing the principles and standards of examination/adjudication with respect to supplementary experimental data adopted by the State Intellectual Property Office of China and courts at various levels in China during the past three years. In addition, the article also includes corresponding provisions and practice of Europe, the US, Japan and Korea as well as puts forward some suggestions in respect of the examination/adjudication in China as related to supplementary experimental data.

I. Determination of Supplementary Experimental Data in China

1. Current provisions

In answering to the call of "Several Opinions of the State Council on Accelerating the Construction of

an IP Power under the New Situation" (Guo Fa No. 71 [2015]), the State Intellectual Property Office of China (SIPO) revised the Guidelines for Patent Examination (the Guidelines), effective from 1 April 2017, stipulating in Section 3 of Chapter 10 in Part II that: "With respect to experimental data submitted after the date of filing, they should be examined by the examiner. The technical effect proved by the supplementary experimental data should be one deducible by a person skilled in the art from the disclosure of the patent application as filed". This revision has removed the statement of "any experimental data submitted after the date of filing shall not be taken into consideration" and provides that experimental data submitted after the filing date shall be considered and examined by the examiner.

This revision of the Guidelines is made principally "only for clarifying the original intent of the provisions of the Guidelines, expressly requesting examination of post-filing experimental data, and ensuring the adherence to the first-to-file principle in the examination of supplementary experimental data. The amendments do not involve any change in examination standards."[1]

In addition, although the provision on supplementary experimental data appears in the section concerning "sufficient disclosure in the description" in the Guidelines, in respect of the submission of supplementary experimental data for proving a technical effect, it is also required to first determine whether the first-to-file principle is satisfied as according to the aforementioned contents made clear in the revision of the Guidelines.[2]

2. SIPO's current examination standards in practice

SIPO usually requests that the technical effect to be proved by supplementary experimental data be directed to the technical effect achieved by the invention as of the filing date, as capable of being known by a person skilled in the art based on the original application documents and the prior art. As to whether a person of ordinary skill in the art is capable of knowing said technical effect as of the filing date, SIPO generally judges it by whether there is explicit disclosure of the original experimental data in the original application documents. That is to say, only if the original application documents have explicitly disclosed the original experimental data of a technical effect can the comparative experimental data relative to the prior art submitted by the applicant or patentee in respect of the technical effect be taken into consideration. If there is no disclosure of the original experimental data of a technical effect in the description, SIPO generally will not allow that said supplementary experimental data be used for proving the inventive step of an invention at the time of filing a patent application, even if there is explicit depiction of relevant technical effect in the

[1] Expert Interpretation of Recent Amendments to the Guidelines of Patent Examination, Lv Dejun et al., China Patents & Trademarks No. 2, 2017, p. 33.

[2] Ibid.

description accompanied by the proof of said technical effect by experimental data or embodiments submitted by the applicant after the filing date.

In order to have an accurate grasp of SIPO's current examination standards on supplementary experimental data submitted after the filing date, we have researched and analysed the reexamination decisions on pharmaceutical cases made by the Patent Reexamination Board (PRB) from early 2015 to the end of 2017. The results are shown in Table 1 (Appendix 1). We derive four circumstances based on the disclosure and acceptance of supplementary experimental data in Table 1 (Appendix 1).

(1) The effect to be proved by the supplementary experimental data is explicitly disclosed in the original description, and relevant data are also disclosed in the original description.

In this circumstance, supplementary experimental data submitted after the filing date are generally considered by SIPO (PRB).

For instance, in Reexamination Decision No. FS129376 (No. 1 of Table 1), the Collegiate Panel held that: "The activity data of the present Compounds No. 19 and No. 20 (17nm and 15nm respectively) against colon cancer cells HCT116 are disclosed in the original description, and can therefore be used for comparison with IC50 value (129nm) of Reference 1's Compound No. 143 against colon cancer cells HCT116 subsequently tested by the reexamination requester. The comparative data demonstrate that the present Compounds No. 19 and No. 20 have substantially enhanced effects against the cytotoxicity of colon cancer cells HCT116 and achieve notable advantageous effects over Reference 1's Compound No. 143."

Notwithstanding the above, the threshold on admissibility of said supplementary experimental data are in fact very strict, and only if the related advantageous effect is clearly demonstrated can the fact to be proved by said data be recognised. For example, in Reexamination Decision No. FS77207 (No. 12 of Table 1), the Collegiate Panel held that: "According to the comparative test data in Attachment 1 submitted by the reexamination requester in response to the Notice of Reexamination, the present Compound No. 15b, compared with the compound of Reference 1, represents a lower value for dopamine D2S receptor, but a higher value for 5-HT1A receptor, and a similar value for 5-HT2A receptor. Since all these three receptors are related to psychosis (see para. [0009] of the present description), said data cannot be used for proving the difference therebetween in terms of the effect of treatment for psychosis."

Moreover, the effect to be proved by said supplementary experimental data will be recognised only if parallel experiments are conducted. For instance, in Reexamination Decision No. FS103917 (No. 7 of Table 1), the Collegiate Panel deemed that: "Although the reexamination petitioner provides the

comparative test data on dissolution effect between the fenofibrate microsphere prepared by the method in Example 2 of the present application and the solid dispersions prepared according to Example 1 of Reference 1, said comparative data are not obtained in parallel experiments, because in the aforesaid comparative experiments, apart from the difference in type and amount of solvent, mixing method and spray drying process, the amounts of HPMC and fenofibrate are also different. Thus, it cannot be judged based on the results of the comparative experiments whether the difference between the two technical solutions in dissolution effect is brought about by the distinction between the method of the present Claim 1 and the method of Reference 1 only, nor can it be proved that all technical solutions comprised in Claim 1 can achieve said technical effect."

(2) The effect to be proved by the supplementary experimental data is explicitly disclosed in the original description, but relevant data are not disclosed in the original description.

In this circumstance, supplementary experimental data submitted after the filing date are generally not considered by SIPO (PRB).

For instance, in Reexamination Decision No. FS73780 (No. 20 of Table 1), the Collegiate Panel opined that: "The requester's depiction of the activity in the description is merely a groundless conjecture. The disclosure contained in the description cannot demonstrate that said technical solution has been confirmed to be capable of achieving the expected effect as of the filing date… In terms of the present application, the compound therein cannot be foreseen to possess said activity based on the prior art, and meanwhile there is no disclosure of any experimental data on effect in the description. Hence, although all of the 32 compounds subsequently submitted fall within the scope of the compounds prepared according to the present description, the supplementary experimental data submitted by the reexamination requester cannot be used for proving that relevant work has been completed and disclosed as of the filing date, thus failing to reverse the insufficiency of disclosure in the description."

There is an example wherein the experiment records have been notarized. In Reexamination Decision No. FS114794 (No. 22 of Table 1), the Collegiate Panel held that: "Albeit the disclosure of the present application that 'a compound of formula (I) and a pharmaceutically acceptable salt thereof exhibiting excellent PDEV inhibitory activities', there is no disclosure of any tested activity data of an exemplary compound in the description. Therefore, a person skilled in the art cannot compare the superiority in activity between the compound of the present application and the compound of Reference 1… The test data in Attachment 1 (i.e. the experimental records that have been notarized by the applicant) submitted by applicant are neither the prior art nor part of the disclosure in the original application documents. These supplementary data are submitted after the filing date; the technical information provided therein is not disclosed in the original application documents or can be proved by the

disclosure therein, nor does it belong to the prior art. Thus, a person skilled in the art cannot attain said technical information by reading the original application documents. And if, in the evaluation of inventive step, the information not contained in the original application documents is taken into consideration, it will extend disclosure of the application documents to include information not originally recited therein, which will violate the first-to-file principle. Hence, such information cannot serve as the basis for the determination of inventive step."

(3) The effect to be proved by the supplementary experimental data is deducible from the original description, but relevant data are not disclosed in the original description.

In this circumstance, supplementary experimental data submitted after the filing date are generally not considered by SIPO (PRB).

For instance, in Reexamination Decision No. FS96530 (No. 36 of Table 1), the Collegiate Panel deemed that: "The requester, when making a request for reexamination, submits Experiment 1 relating to the compound's solubility in aqueous buffers with different PH values and Experiment 2 on purification of the compound under certain conditions. However, a compound has many physical and chemical properties including but not limited to water solubility, liposolubility and oxidability, but the present description does not disclose any technical content or experimental data relating to purification or solubility of the compound of formula (4). Thus, even if there is generalised disclosure such as "the present invention exhibits enhanced physical and chemical properties" in the original description, as asserted by the requester in the Observations, it cannot be determined thereby that the experiment subsequently submitted by the requester has been disclosed or completed as of the filing date of the present application. Hence, the data in Experiment 1 and Experiment 2 cannot be considered."

Another example is Reexamination Decision No. FS125512 (No. 34 of Table 1), wherein the Collegiate Panel stated that: "The present description mentions under Summary of the Invention that ‘the present invention is directed to novel compounds capable of modulating the stability and/or activity of hypoxia inducible factor (HIF) and a method for using said compounds' (see para. [0007]), and correspondingly discloses the methods for determining the biological activity of the compounds in the section on Biological Testing under Part 5 of Testing and Administration... The Observations filed by the reexamination requester in response to the Notice of Reexamination contain comparative experimental data between some exemplary compounds of the present application and Compound B of Reference 1 on EGLN1-inhibiting IC50 values as well as increased EPO levels measured by HIF-PH assay. The requester contends that the present description has disclosed the following: said compounds have the technical effects of modulating the stability and/or activity of HIF; inhibition of HIF prolyl hydroxylase enzymes can stabilise HIF; and HIF prolyl hydroxylase enzymes include

EGLN1…, and therefore, the IC50 value of EGLN1 should be considered as capable of overcoming the lack of inventive step. With regard to said supplementary experimental data submitted, the Collegiate Panel holds that as stated above, the present description discloses the assays for determining the biological activity of the compounds only in the section on Biological Testing under Part 5 of Testing and Administration, and just briefly mentions that 'the compounds of the invention are active in at least one of these assays', which shows that the present application has only disclosed such technical effects as the present compounds being capable of modulating the stability and/or activity of HIF, but does not contain data on the compounds' effects on inhibiting EGLN1 and/or increasing EPO levels. While the supplementary experimental data submitted by the reexamination requester include the data of the present compounds' IC50 values in inhibiting EGLN1 and their effects in increasing EPO levels, such data are not disclosed in the present application documents. Therefore, a person skilled in the art, based on the disclosures contained in the present application and Reference 1, cannot reach the conclusion that the present compounds have superior effects over the compound of Reference 1 in inhibiting EGLN1 and increasing EPO levels, as intended to be illustrated by said data."

(4) The effect to be proved by supplementary experimental data is not explicitly disclosed in the original description, and relevant data are not disclosed in the original description either.

In this circumstance, supplementary experimental data submitted after the filing date are generally not considered by SIPO (PRB).

For instance, in Reexamination Decision No. FS126730 (No. 39 of Table 1), the Collegiate Panel held that: "Said comparative test data submitted are not disclosed in the original application documents; moreover, a person skilled in the art, based on the original application documents in combination with the prior art, cannot determine or attain the aforesaid test results and conclusion. Thus, said data have exceeded the scope of the disclosure contained in the original application documents and cannot serve as the evidence for proving that the present compound has unexpected technical effects."

Similarly, in Reexamination Decision No. FS124697 (No. 41 of Table 1), the Collegiate Panel stated that: "The reexamination requester submitted Attachments 10-13 to prove the technical effect of CAI orotate via oral administration. The Collegiate Panel, after a careful review of said supplementary experimental evidence, deems that the technical effect to be proved by said data neither has been disclosed in the original application documents, nor can be attained by a person skilled in the art based on the original disclosure of the present patent application. Hence, the supplementary experimental data submitted by the reexamination requester cannot prove an inventive step of the present application."

We generate Table 2 as below after conducting statistics on the data of Table 1 (Appendix 1).

Table 2

	No. of cases	**No. of cases in which supplementary data are considered**	**No. of cases in which supplementary data are not considered**	**Percentage of No. of cases in which supplementary data are not considered**
Circumstance (1)	12	6	6	50%
Circumstance (2)	21	1	20	95%
Circumstance (3)	3	0	3	100%
Circumstance (4)	12	0	12	100%
Total	48	7	41	85%

From Table 2 above, it is known that:

(i) Currently, supplementary experimental data submitted after the filing date for proving the technical effect of an invention are very unlikely to be considered by SIPO (PRB);

(ii) As long as no relevant experimental data are disclosed in the original application documents, SIPO (PRB) will generally not consider the supplementary experimental data regardless of whether the technical effect has been expressly recited in the original description;

(iii) Even if the technical effect and relevant data are expressly recited in the original description, if, compared with a reference, the supplementary experimental data are not obtained via parallel experiments or cannot exhibit an advantageous technical effect, said data can still be not considered.

3. Determination standard of the Chinese courts

In respect of post-filing experimental data, the Chinese courts have also set down some adjudication standards. For instance, Several Legal Issues to Note in IP Adjudication (2017) issued by the Beijing Higher People's Court (BHPC) states that the latest amendments of the Guidelines as mentioned above "have changed the examination approach from a conservative, rigid one toward better balancing the maintenance of the first-to-file principle and the protection of the interest of the patentee, and BHPC further provides therein its interpretation on said amendments: "First, the technical effect to be proved by the supplementary experimental data must be explicitly stated in the original patent application documents, and the facts supported by said data must not go beyond the scope of the disclosure of the original application documents, i.e. such data may not be used for proving any new technical facts; second, the same criteria for admissibility of supplementary evidence applies, regardless of whether the supplementary experimental data are filed for overcoming insufficiency of disclosure in the description or proving the inventive step of a patent; third, notwithstanding the appearance of the

contents about supplementary experimental data in the section on examination of chemistry invention in the Guidelines, the provisions are applicable to other technical fields as well; fourth, the experimental data are obtained based on the experimental conditions, facilities, and experimental means as of the filing date."

The Supreme People's Court of China (SPC) also pointed out in its ruling [3] that: "Regarding those post-filing experimental evidence for proving the sufficiency of disclosure in the description, if it can be proved that a person skilled in the art, given his knowledge level and cognitive ability as of the filing date, may realise the invention based on the disclosure of the description of the experimental evidence, the experimental evidence should be taken into consideration and should not be rejected merely because they are submitted after the filing date. In considering the admissibility of experimental data, time factor and the subject should be rigorously examined. In terms of time factor, the experimental conditions and methods related to the experimental evidence should be directly derivable or easily conceivable by a person skilled in the art from the description as of the filing date or priority date; in terms of subject, consideration should be based on the knowledge level and cognitive ability of a person skilled in the art.

The SPC in Article 13 of the Provisions on Several Issues Concerning the Trial of Administrative Cases Involving Patent Grant and Affirmation (I) (Draft for Comments) states that: (1) In case of post-filing experimental data in respect of a chemistry invention submitted by a patent applicant or patentee in support of sufficiency of disclosure of a technical effect in the description, where the experimental conditions and methods related to the experimental data have been explicitly stated in the prior art or can be directly and unambiguously determined by a person skilled in the art from the description and drawings, the court generally shall accept the experimental data, unless the technical effect stated in the patent application documents as of the filing date is unable to be confirmed by the person skilled in the art; (2) In case of post-filing comparative experimental data in respect of a chemistry invention submitted by a patent applicant or patentee for proving a technical effect being distinct from that of a reference, where the technical effect is deducible by a person skilled in the art from the disclosure of the patent application documents, the court generally shall accept the experimental data.

As seen from the above provisions and rulings, the courts seem to be of the opinion that SIPO (PRB) has taken too conservative and rigid an approach in the examination of post-filing experimental data, and deem that supplementary experimental data should be considered provided certain conditions have been satisfied.

In order to have a better grasp of the courts' view in this matter, we have researched on the rulings

[3] The Supreme People's Court's Judgment No. Xingtizi 8/2014

related to supplementary experimental data made by Beijing Intellectual Property Court (BIPC), BHPC, and SPC during the period between 2014 and 2017. The results of our research are shown in Table 3 (Appendix 2). Similarly, we have also derived four circumstances based on the disclosure and acceptance of supplementary experimental data in Table 3 (Appendix 2) as follows:

(1) The effect to be proved by the supplementary experimental data is explicitly disclosed in the original description, and relevant data are also disclosed therein.

In this circumstance, it is likely that the applicant's point will be taken, and hence no administrative litigation ensues in general. In fact we did find no occurrence of such litigation among the rulings we have researched.

(2) The effect to be proved by the supplementary experimental data is explicitly disclosed in the original description, but relevant data are not disclosed therein.

In this circumstance, the post-filing experimental data are generally not considered by both the courts and SIPO (PRB).

For instance, in *Bristol-Myers Squibb Company and ZymoGenetics, Inc. v. PRB* (Third party: Tri-Prime Gene Engineering Co., Ltd.) [4], BHPC deemed that Exhibit 10 and Exhibit 11 (supplementary experimental data and a thesis paper respectively) submitted for the litigation lacked probative value as the publication date of the exhibits was subsequent to the filing date of the patent at issue.

In *Boehringer Ingelheim Pharma GmbH & Co.KG v. PRB* [5], BHPC opined that the COPD-curing property of the compound recited in the patent at issue, i.e. the compound's possession of beta quasi-drug activity for curing COPD, was merely an inference; there was no technical information disclosed in the present description to prove that Compound No. 1a possessed said advantageous effect, not to say the exceptional strength and high selectivity as claimed. As a result, relevant supplementary data were not accepted in this case.

(3) The effect to be proved by the supplementary experimental data is deducible from the original description, but relevant data are not disclosed therein.

We did not locate any relevant rulings relating to this circumstance; however, we can infer from other court rulings that the post-filing experimental data are generally not considered by both the courts and

[4] Judgment No. Gaoxingzhongzi 1127/2014
[5] Judgment No. Jingxingzhong 3668/2017

SIPO (PRB) under this circumstance.

(4) The effect to be proved by supplementary experimental data is not explicitly disclosed in the original description, and relevant data are not disclosed therein either.

In this circumstance, the post-filing experimental data are generally not considered by both the courts and SIPO (PRB).

For instance, in *Shandong Xinshidai Medicine Industry Co., Ltd. v. PRB* [6]*, BHPC* held that: "Where the applicant submits comparative experimental data for proving the inventiveness of the claimed technical solution over the prior art, the premise for the consideration of such data is, the data must be directed to the technical effect already explicitly disclosed in the original application documents; that is, if the experiment effect to be proved by the supplementary experimental data is not mentioned at all in the original application documents, the experimental data will not be taken into consideration. As the experiment effect to be proved by the supplementary experimental data submitted by Shandong Xinshidai Medicine Industry Co., Ltd. in the first-instance ruling is not mentioned explicitly in the original application documents, the supplementary experimental data filed by the company in this case cannot be taken into account."

Similarly, we have generated Table 4 as below after conducting statistics on the data of Table 3 (Appendix 2).

Table 4

	No. of cases	**No. of cases in which supplementary data are considered**	**No. of cases in which supplementary data are not considered**	**Percentage of No. of cases in which supplementary data are not considered**
Circumstance (1)	0	0	0	0%
Circumstance (2)	12	1	11	92%
Circumstance (3)	0	0	0	0%
Circumstance (4)	3	0	3	100%
Total	15	1	14	93%

From Table 4 above, it is known that:

(i) Currently, supplementary experimental data submitted after the filing date for proving the technical effect of an invention are very unlikely to be considered by the court in trial;

[6] Judgment No. Jingxingzhong 3046/2017

(ii) Consistent with the SIPO (PRB) standard, the courts' practice is that as long as no relevant experimental data are disclosed in the original application documents, supplementary experimental data are generally not considered by the courts regardless of whether the technical effect is expressly recited in the original description.
(iii) Although the courts have set down some rules relating to the adjudication of supplementary experimental data, these rules are in practice highly consistent with the examination standards of SIPO (PRB). As of this writing, we have found no rulings that have actually reversed PRB's decisions and considered the supplementary experimental data submitted.

II. Comparisons with Relevant Provisions in Other Countries

As for the examination of the experimental data supplemented after the filing date, there are relevant provisions and cases in other countries and regions. We mainly introduce the relevant provisions and cases in United States, Europe, Japan and South Korea and compare them with relevant provisions of China.

1. The United States[7]

It is prescribed inSection 716 of the *Manual of Patent Examining Procedure* (MPEP) about "Affidavits or Declarations Traversing Rejections, 37 CFR 1.132 [R-11.2013]":

716.01(a) Objective Evidence of Nonobviousness

Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under **35 U.S.C. 103**. The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may be decisive. See *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer,* 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder,* 471 F.2d 640, 176 USPQ 300

[7] For details, please refer to Provisions of the Guidelines for Examination of the U.S., and Judgment of the Zenitz case.

(CCPA 1973).

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. See *In re Margolis,* 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). The lack of objective evidence of nonobviousness does not weigh in favor of obviousness. See *Miles Labs. Inc. v. Shandon Inc.,* 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993), *cert. denied,*127 L. Ed. 232 (1994). However, where a *prima facie* case of obviousness is established, the failure to provide rebuttal evidence cannot reverse the decision.

716.01(b) Nexus Requirement and Evidence of Nonobviousness

TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams,* 383 U.S. 39,148 USPQ 479 (1966).

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. See *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.,* 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied,*475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. See *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.,* 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied,* 488 U.S. 956 (1988).

716.02(f) Advantages Disclosed or Inherent

The totality of the record must be considered when determining whether a claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore,

evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded. *In re Chu*, 66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995) (Although the purported advantage of placement of a selective catalytic reduction catalyst in the bag retainer of an apparatus for controlling emissions was not disclosed in the specification, evidence and arguments rebutting the conclusion that such placement was a matter of "design choice" should have been considered as part of the totality of the record. "There is no case supporting the position that a patent applicant's evidence or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of ex parte patent prosecution." 66 F.3d at 299, 36 USPQ2d at 1095.). See also *In re Zenitz*, 333 F.2d 924, 928, 142 USPQ 158, 161 (CCPA 1964) (evidence that claimed compound minimized side effects of hypotensive activity must be considered because this undisclosed property would inherently flow from disclosed use as tranquilizer); *Ex parte Sasajima*, 212 USPQ 103, 104 - 05 (Bd. App. 1981) (evidence relating to initially undisclosed relative toxicity of claimed pharmaceutical compound must be considered).

It can be seen from the above provisions under the Guidelines for Examination of the U.S. that the experimental data supplemented by the applicant after the application date for proving the effect should be taken into consideration.

For example, in the above Zenitz's case mentioned in MPEP, the applicant of the patent held that "not only are the trifluoromethyl compounds considerably more active as tranquilizers and sedatives than the corresponding *749 chloro and unsubstituted compounds as shown above but also show considerably less undesirable side effects, such as a hypotensive effect, making them superior with respect to decreased side effects than either the corresponding chloro compounds or the unsubstituted compounds. A hypotensive effect alone is useful in compounds that are to be used specifically to lower the blood pressure, but when this property is also possessed by compounds used as tranquilizers or sedatives, it is regarded as a serious side-effect which can cause other side-effects such as dizziness or blurring of vision. Its minimization or complete elimination in compounds to be used as sedatives and tranquilizers is, therefore, to be desired". With respect to the above opinion of the applicant, the Board of Patent Appeals deemed that since "the separation of hypotensive from tranquilizing effect" was not originally disclosed, the examiner, citing In re Stewart, 222 F.2d 747, 42 CCPA 937, held that Zenitz could not now rely on that effect as a ground for establishing unobviousness. The board agreed.

However, the Court of Patent Appeals rejected the above opinion of the examiner and the Board of Patent Appeals, holding that "In the above case, Zenitz disclosed his compounds to be useful as tranquilizers as well as hypotensives, sedatives, etc. It is true that the present application did not mention the separation of hypotensive and tranquilizing activity, but same as the celluloid top in the Westmoreland case, the advantage of the minimization of the hypotensive activity is brought by the use of the compounds as sedatives itself. Zenitz disclosed a tranquilizer and subsequently established that if it is used as a tranquilizer it is a better one for it minimizes the side effects of hypotensive activity. Therefore, we think the latter property must be considered in determining the patentability of the claimed compound." Based on this, the Court of Patent Appeals made the following judgement: the rejection of claims 3, 9, 10 and 11 shall be reversed.

2. Europe[8]

It is stipulated in Chapter G-VII 11 of the *Guidelines for Examination in the European Patent Office* that: the relevant arguments and evidence to be considered by the examiner for assessing inventive step may either be taken from the originally-filed patent application or submitted by the applicant during the subsequent proceedings (see G-VII, 5.2, and H-V, 2.2 and 2.4). Care must be taken, however, whenever new effects in support of inventive step are referred to. Such new effects can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application (see also G-VII, 5.2, T 386/89 and T 184/82).

Example of such a new effect: The invention as filed relates to a pharmaceutical composition having a specific activity. At first sight, having regard to the relevant prior art, it would appear that there is a lack of inventive step. Subsequently, the applicant submits new evidence which shows that the claimed composition exhibits an unexpected advantage in terms of low toxicity. In this case, it is allowable to reformulate the technical problem by including the aspect of toxicity, since pharmaceutical activity and toxicity are related in the sense that the skilled person would always contemplate the two aspects together. The reformulation of the technical problem may or may not give rise to amendment or insertion of the statement of the technical problem in the description.

In addition, "Comparative test" is mentioned in Chapter I.D.10.9 of *Case Law (2016)*, which stipulates that:

[8] For details, please refer to Provisions of the Guidelines for Examination in the EPO and Provisions of European Case Law.

According to the established jurisprudence, a surprising effect (advantageous effect or feature) demonstrated in a comparative test can be taken as an indication of inventive step. If comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect, the nature of the comparison with the closest state of the art must be such that the alleged advantage or effect is convincingly shown to have its origin in the distinguishing feature of the invention compared with the closest state of the art (**T 197/86**, OJ 1989, 371; **T 234/03**; **T 378/03**) and alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention (see also Chapter I.D.4.2 "Alleged advantages"; **T 20/81**, OJ 1982, 217; **T 561/94**).

In **T 197/86** (OJ 1989, 371) the board supplemented the principles laid down in earlier decision **T 181/82** (OJ 1984, 401), according to which, where comparative tests were submitted as evidence of an unexpected effect, there had to be the closest possible structural approximation in a comparable type of use to the subject-matter claimed. In the case in point the respondent (proprietor of the patent) strengthened support for his claim by voluntarily providing comparisons with variants which, although not expressly belonging to the prior art, differed from the claimed subject-matter only by the distinguishing feature of the invention. The board summarised its position by stating, that in cases where comparative tests were chosen to demonstrate an inventive step with an improved effect over **a claimed area**, the nature of the comparison with the closest state of the art had to be such that the effect was convincingly shown to have its origin in the distinguishing feature of the invention. For this purpose it might be necessary to modify the elements of comparison so that they differed only by such a distinguishing feature (**T 292/92, T 412/94, T 819/96, T 133/01, T 369/02, T 668/02, T 984/03, T 2043/09).**

As early as **T 35/85** the board had stated that an applicant or patentee may discharge his onus of proof by voluntarily submitting comparative tests with newly prepared variants of the closest state of the art identifying the features common with the invention, in order to have a variant lying closer to the invention so that the advantageous effect attributable to the distinguishing feature is thereby more clearly demonstrated (**T 40/89**, **T 191/97**, **T 496/02**).

It is for the applicant (patentee) to furnish evidence of an improved effect of the subject-matter of a claim, which has been asserted, but was not mentioned in the application as filed, in the whole of the claimed area vis-à-vis the closest prior art (**T 355/97**, **T 1213/03**,**T 653/07**).

In **T 234/03** the board stated that to be of relevance in demonstrating that "a technical improvement is achieved in comparison with the closest state of the art", any comparative test presented must be reproducible on the basis of the information thus provided, thereby rendering the results of such tests directly verifiable (**T 494/99**). This requirement implies, in particular, that the procedure for performing the test relies on quantitative information enabling the person skilled in the art to reproduce it reliably and validly. Vague and imprecise operating instructions render the test inappropriate and thus irrelevant.

3. Japan

It is stipulated in Part I, Chapter 2, Section 4.2.1.1 of the *Examination Guidelines for Patent and Utility Model in Japan* that a written opinion or certificate of supplementary experimental results are no substitute for "Detailed Description of the Invention" in the description. However, these are submitted to clarify or verify that matters stated in the originally-attached description, etc., are correct and reasonable. Therefore, when the written opinion or certificate of supplementary experimental results are submitted, the examiner shall sufficiently take details of them into account.

In addition, it is stipulated in Part III, Chapter 2, Section 2.3.2.1 (2) of the *Examination Guidelines for Patent and Utility Model in Japan* that in the following case (i) or (ii), the examiner should consider the advantageous effects over the prior art argued and proved in the written opinion (e.g. supplementary experimental results), etc. (i) Case where these effects are stated in the description (ii) Case where these effects are not stated in the description, but can be speculated by a person skilled in the art from the description or drawings. However, the examiner should not take these effects into consideration where these effects are not stated in the description and cannot be speculated by a person skilled in the art from the description or drawings.

It can be seen from the above provisions in the *Examination Guidelines for Patent and Utility Model in Japan* that as long as relevant effects are disclosed in the original application documents, the experimental data supplemented by the applicant after the filing date for demonstrating the effects shall be taken into consideration.

For example, in a reexamination case 2007-5283, for demonstrating the inventive step of the amended claims, the applicant added supplementary experimental data in the supplementary statement for the

request for reexamination. With regard to the supplementary experimental data, Japan Patent Office (JPO) deemed that, paragraph [0011] of the description in the present application merely provides a general description of the effect of the present invention, and how high the SPF value or PPD value cannot be presumed from the original description of the present application. In the context of the determination as to whether the present invention has inventiveness, absent any special circumstances, in the event there is no description with regard to the "effect of invention" in the original description, it should not be allowable to claim and/or prove [such effect] by submitting supplementary experimental results after filing of the application, since such act is against the objectives of the patent system, which takes the first-to-file principle and grants the patent right (exclusivity) in compensation for the disclosure of the invention.

With regard to the above assertions presented by JPO, the Intellectual Property High Court of Japan issued a judgment 2009 (Gyo-ke) 10238[9] on July 15, 2010 in which the above assertions presented by JPO were denied and relevant contents were provided as follows.

This court holds as follows.

(1) There is an error in the JPO reexamination decision ruling said experimental results should not be taken into consideration.

(2) By taking said experimental results into consideration, the claimed invention can be found to achieve an unexpected, remarkable effect that a person ordinarily skilled in the art could not have expected as compared with the cited prior invention, and it is deemed that the claimed invention could not have easily been conceived of by referring to the cited prior invention. Consequently, there is an error in the JPO reexamination decision ruling that the claimed invention could not achieve any unexpected, remarkable effect but could have been easily conceived by referring to the cited prior invention.

The court provided the following reasons for the above assertions.

(1) In the context of the determination of the inventive step, because the reasons for not allowing consideration of the experimental results of the "effect of invention", etc. that are supplemented after its application come from the objects of the patent system and the needs for fairness between the

[9] For details, please refer to Judgment.

applicant and the third parties, etc., hence in the case where there is no description of the “effect of invention” in the original description but there is some description enough for a person ordinarily skilled in the art to recognize or pressumed the “effect of invention” therein, it should be allowable to take into consideration experimental results, etc. that are supplemented after its application as long as they are considered only within the scope presented in said description.

(2) Indeed, the original description of the present application does not explicitly disclose the remarkable effects according to the experimental results presented in [Reference 1]. However, in the present case, after reading the original description, a person ordinarily skilled in the art can recognize that the present invention has an effect of further improving broad spectrum UV efficacy and photostability. Therefore, it is allowable to take into consideration the experimental results, etc. that are supplemented after the application in the context of the determination of the inventive step, and even doing so does not cause unfairness between the applicant and the third parties.

(3) Supposed if the defendant’s (JPO) assertion was followed, in case where the effect is described in a qualitative manner or its value is not clearly disclosed in the original description of the present application, it would be pressumed that the effect of the present invention is not disclosed and the experimental results that are supplemented after the application cannot be taken into consideration. Considering that an applicant is not able to know which cited prior invention will be compared with the claimed invention in the future and the reasoning held by the examination body etc. at the time of the application, such conclusion will cause excessive burden on the applicant, forcing it to lose its chance of objective verification based on the experimental results, and will violate the objective of fairness mentioned above. Therefore, such position cannot be taken.

4. Korea

It is stipulated in Supreme Court Case 2000 Hu 3234 that, "Articles 29(1)(ii) and 29(2) of the Korean Patent Act prescribe that an invention described in a publication distributed in or outside Korea prior to the filing date of the patent application, or a creation which could have easily been conceived from the prior art, lacks novelty and/or inventiveness and cannot be patented. According to these provisions, the difficulty in creating the invention, which is a basis for determining inventiveness, should be assessed by considering the technical constitution and the working effect. Accordingly, if an invention has a different technical constitution from the prior art, and has a remarkably improved working effect over the prior art, the inventiveness of the invention should be acknowledged in view of the purpose

of the patent system to encourage technical developments (see Supreme Court Case 97 Hu 44; December 9, 1997, and Supreme Court Case 97 Hu 2033; April 9, 1999, etc.). If the improved effect of an invention is not explicitly described in the specification, but can be inferred from the descriptions in the specification by those skilled in the art, then such a working effect should still be considered in determining the inventiveness of the invention."

It is stipulated in Patent Court Case 2006 Heo 8958 that, "The Plaintiff argues that although the effect as described above is not explicitly described in the specification, it should be considered in determining the inventiveness of the invention since a person skilled in the art can easily be aware of said effect from the descriptions in the specification. Thus, the Court first determines whether Plaintiff's asserted working effect can be considered when assessing the inventiveness of the invention of Claim 12. In principle, if a working effect is not described in the patent specification, such an effect should not be considered in assessing the inventiveness of the invention (see Supreme Court Case 96 Hu 221; May 30, 1997). However, even if the working effect of the invention is not disclosed in the specification, the effect still can be considered in assessing inventiveness if the effect can be inferred from the descriptions in the specification by a person skilled in the art (see Supreme Court Case 2000 Hu 3234; August 23, 2002)."

5. Comparison with China

In order to understand the provisions for the supplementary experimental data in the United States, Europe, Japan, Korean and China, the provisions in each nation/region is summarized in the following Table 5.

Table 5

Nation/Region	Related Provision and Decision
China	The technical effect proved by the supplementary experimental data should be one that can be derived by a person skilled in the art from the disclosure of the patent application.
The United States	Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability (including the supplementary experimental data).

	Evidence of secondary considerations (including the supplementary experimental data) must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. Evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded.
Europe	The effects proved by the supplementary experimental data can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application.
Japan	In the following case (i) or (ii), the examiner should consider the advantageous effects over the prior art argued and proved in the written opinion (e.g. supplementary experimental results), etc. (i) Case where these effects are stated in the description (ii) Case where these effects are not stated in the description, but can be speculated by a person skilled in the art from the description or drawings.
Korea	If an invention has a different technical constitution from the prior art, and has a remarkably improved working effect over the prior art, the inventiveness of the invention should be acknowledged. If the improved effect of an invention is not explicitly described in the specification, but can be inferred from the descriptions in the specification by those skilled in the art, then such a working effect should still be considered in determining the inventiveness of the invention.

From Table 5 above, it seems, at least literally, there is not much difference in the provisions on examination of supplementary experimental data among patent offices of various jurisdictions, including China, in the sense that they all contain the stipulation that post-filing experimental data in support of a technical effect will be considered as long as the technical effect can be derived by a person skilled in the art based on the disclosure of the original application documents.

However, in examination/adjudication practice, the patent office in China, compared with its counterparts in the US, Europe, Japan, and Korea, is more unlikely to consider supplementary experimental data. In particular under the circumstances where the technical effect is explicitly disclosed in the original description but no relevant experimental data are disclosed therein, or where the technical effect is deducible from the disclosure of the original description but no relevant experimental data are disclosed therein, it is almost impossible that post-filing experimental data in

support of said technical effect of the invention will be considered according to prevalent practice in China, while in contrast, post-filing experimental data under similar circumstances would be considered by patent offices in the US, Europe, Japan, and Korea, as is shown in the decisions and judgments of the cases under Part II of this article.

In our opinion, the reason for this phenomenon lies in the overly strict interpretation of SIPO and the Chinese courts on the provisions of the Guidelines that "the technical effect to be proved by the supplementary experimental data should be derivable by a person skilled in the art from the disclosure of the patent application". As is shown in the decisions and judgments of the cases under Part I of this article, SIPO and the Chinese courts are of the opinion that if relevant experimental data are not provided in the original description, the technical effect cannot be deemed as having been confirmed as of the filing date. Given that the effect has not been confirmed as of the filing date, said effect cannot be deemed as being derivable from the original application documents from the perspective of the first-to-file principle.

In other words, in China, even if a technical effect has been explicitly disclosed in the original description or said effect can be deduced therefrom, as long as the experimental data for proving the effect are not disclosed in the original description, said effect will not be deemed as "derivable form the disclosure of the patent application by a person skilled in the art". Accordingly, even if post-filing experimental data are submitted for proving the effect, they will not be taken into consideration.

Admittedly, the first-to-file principle and the disclosure-in-exchange-for-protection principle are the rudimentary principles of the patent law. However, judging from current examination/adjudication standards of SIPO and the Chinese courts, the objective fact that the technical effect has been expressly recited in the original patent application documents or is deducible from the disclosure of the original application documents has obviously been overlooked. Original application documents are legal documents for expounding an invention, and given that the objective fact has been included in said legal documents as of the filing date, supplementary experimental data for supporting such objective fact should certainly be taken into consideration.

Moreover, SIPO and the Chinese courts may also be bothered by the concern that allowance of post-filing experimental data could result in unfairness to the third party, thus hampering the third party from further attempts on inventions and creations. Regarding this concern, our thinking is that since the technical effect has already been explicitly disclosed in the original patent application documents or is deducible from the disclosure thereof, it can be reasonably believed that sufficient technical inspiration for the technical effect has been provided in the original patent application documents, and under this circumstance, it is impossible for the third party to get a patent for said technical effect. Quite the contrary, if submission of supplementary experimental data by the patent

applicant for proving the technical effect is allowed, the third party can be benefited from a full understanding of the art of the invention.

III. Problems and Suggestions

1. Problems caused by strict examination/adjudication on supplementary experimental data

As mentioned before, at present post-filing experimental data have to undergo strict examination or adjudication, whether by SIPO or courts at various levels in China. We find that such strict examination or adjudication could cause undesirable influence in the following ways.

(1) As a member of the world's five major IP offices (IP5), SIPO is practicing on an examination standard different from other members including USPTO, EPO, JPO, and KIPO with respect to post-filing experimental data.

In the latest meeting of the heads of IP5 Office held in 2017, a new vision of cooperation among the five offices has been agreed upon with a view to promoting a more efficient, cost-effective and user-friendly international patent landscape in the aspects of: pursuing efforts toward harmonisation of patent practices and procedures; enhancing work-sharing; providing high-quality and timely search and examination results; and seamless access to patent information. To this end, IP5 have established an expert panel committed to exploring the coordination of patent practices and procedures, launching research on relevant work and providing expert opinions, conducting case studies on unity of patent, citing of prior art and description/sufficient disclosure, with an attempt to compare the similarities and differences in examination practice of IP5 on the basis of similar cases, and explore the possibility of coordination at the practical level.

As a member of IP5, SIPO also takes an active part in related initiatives to work toward the consistency of examination criteria among the five IP offices in general direction. In such circumstance, SIPO's exercise of overly strict examination criteria on post-filing experimental data that are obviously different from those of other IP5 members is set to affect the image of SIPO as one of the world's major IP offices and in turn its status in IP5.

(2) Strict examination standards on supplementary data are not conducive to invention and innovation, and hamper the nation's technological development in the field of chemistry, especially the pharma industry.

The legislative purposes of the Patent Law are to encourage inventions and creations, advance the exploitation of inventions and creations, and enhance innovation capability. And the patent system is

designated to encourage early disclosure of inventions, thus enabling the public to learn about the disclosed inventions as early as possible and conduct further researches on that basis. Obviously, strict examination standards on supplementary data will be adverse to the intention of encouraging innovation and creation, thus hampering the technological development of the country in the field of chemistry, especially the pharma industry.

(3) Overly strict criteria on examination/adjudication of supplementary experimental data create too heavy and unreasonable burden to the applicant.

Upon the filing of a patent application, it is out of the applicant's reach to exhaust all of the relevant prior art with a comprehensive command of prior art, nor should they be expected to foresee the status of search on reference documents by the patent examiner during the substantive examination, what previous inventions would be used for comparison, and what reasons will be put forward by the examiner. For these reasons, it is difficult for the applicant to provide pertinent experimental data.

This issue is more prominent in the pharma field, due to the prolonged product research cycle and massive experimental data. The applicant at the time of drafting the application documents may not be able to foresee or search in advance the closest prior art recognised during the examination process. And in reality it is next to impossible to present the effects and provide experimental data based on the entire prior art.

The harsh examination criteria and such line of thinking can overburden the patent applicant and patentee, thus dampening the inventor's initiative to file patent applications, which is not conducive to invention and innovation and hampers technological progress.

(4) Overly strict criteria on examination/adjudication of supplementary experimental data affect not only the development of domestic and foreign pharma enterprises, but also the initiative of the enterprises in conducting R&D of new drugs.

Overly strict criteria on examination/adjudication of supplementary experimental data make it difficult for foreign pharma companies to get patents in China, and accordingly competitive power of their invented products in the country will be affected, the direct consequence of which is an impact on investment of foreign pharma companies in China. Recent years see the successive downsizing of certain internationally renowned pharma companies' R & D centers in China. While the reasons for this phenomenon are many, part of them is related to the foreign companies' concern about the IP protection environment in China, especially in such aspects as patent filing, "patent disputes, and institution and adjudication of cases at the court".[10]

[10] Renowned Multinational Pharma Companies Rushing to Leave China? Mixed Causes Behind the

Overly strict criteria on examination/adjudication of supplementary experimental data not only undermine the initiative of foreign pharma companies, but also hinder that of the domestic pharma industry in R&D of new drugs, which is adverse to Chinese pharma industry's transformation into an innovative industry. Failure to have core patents granted in China's pharma industry will affect considerably the capital-raising of innovative enterprises.

In brief, overly strict criteria on examination/adjudication of supplementary experimental data have an adverse effect on the overall investment environment of China, which are not conducive to foreign investment as well as domestic enterprises' capital raising, and as a result posing a negative impact on economic development in China.

(5) Overly strict criteria on examination/adjudication of supplementary experimental data may undermine the public's health choices.

Overly strict criteria on examination or adjudication of supplementary experimental data will inevitably make it difficult for many pharma companies to get patents in China for their invented products. The operation of pharma companies specialising on new drugs are highly dependent on expected patent grants. If new drug patent applications are unable to get granted in China, these pharma companies' enthusiasm to introduce new drugs to China will be dampened, and this will in turn affect the accessibility of new drugs for the patients in China, thus undermining the health choices of the nation.

2. Suggestions

In this concluding section of our article, we attempt to put forward some suggestions on how the foregoing problems as identified can be addressed or mitigated.

In respect of supplementary experimental data submitted after the filing date for proving an effect, i.e. the subject of our article, we suggest that they should be considered during the examination/adjudication of a patent application where said effect is explicitly disclosed in the original description or is deducible from the disclosure thereof despite no disclosure of relevant experimental data in the original description.

SIPO and Chinese courts may have the concern that allowing the submission of supplementary experimental data after the filing date might result in unfairness to the third party and thus hinder the third party's further attempts on invention or creation. However, since said effect has already been explicitly disclosed in the original application documents of the invention or is deducible from the

disclosure thereof, it can be reasonably believed that sufficient technical inspiration for the technical effect has been provided in the original application documents, and under such circumstance, it is impossible for the third party to get a patent for said technical effect. Quite the contrary, if submission of supplementary experimental data by the patent applicant for proving the technical effect is allowed, the third party can be benefited from a full understanding of the art of the invention.

In light of this, we believe that, by adopting the examination standards as we suggest above, China can have its examination standards consistent with those of other countries and regions, and additionally, inventions and creations can get more extensive and stronger protection in China so as to ensure the advancement of science and technology in the country.

Appendix 1

Table 1 Reexamination decisions on pharmaceutical cases made by the Patent Reexamination Board (PRB) from early 2015 to the end of 2017

No.	Judgment No.	Applicant	Application No. / Publication No.	Whether the effect proved by supplementary experimental data is mentioned in the original description	Whether the effect proved by supplementary experimental data is deducible from the original description	Whether relevant data are disclosed in the original description	Whether supplementary data are considered	Result of ruling
1	FS129376	German Cancer Research Cente (DKFZ), Ruprechts-Karls -Universität Heidelberg	CN201180064964(A) CN103328463(A)	Yes	-	Yes	Yes	Decision of rejection revoked
2	FS123930	Nihon Medi-Physics Co., Ltd.	CN201280027545(A) CN103596950(A)	Yes	-	Yes	Yes	Decision of rejection revoked
3	FS110886	Akaal Pharma Pty Ltd.	CN200980141188(A) CN102186845(B)	Yes	-	Yes	Yes	Decision of rejection revoked after amendment

4	FS95454	Sunesis Pharmaceuticals, Inc., Millennium Pharmaceuticals, Inc.	CN200880022788(A) CN101784545(A)	Yes	-	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: Notarized experiment record considered	Decision of rejection revoked after amendment
5	FS89092	Celgene Corporation	CN200780036550(A) CN101583359(A)	Yes	-	Yes	Supplementary experimental data not mentioned in the description, given sufficiency of disclosure in the description	Decision of rejection revoked
6	FS95698	The Council of Scientific & Industrial Research	CN200980152325(A) CN102264716(A)	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: -	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: Yes	Decision of rejection revoked after amendment
7	FS103917	Samyang Biopharmaceuticals Corporation	CN201080029072(A) CN102458373(A)	Yes	-	Yes	Effect not recognised for not being parallel experiments	Decision of rejection upheld

8	FS103243	AbbVie Inc., Abbvie Deutschland GmbH & Co. KG	CN201080064024(A) CN102753541(A)	Yes	-	Yes	Effect and authenticity not recognised	Decision of rejection upheld
9	FS99656	The Hong Kong Polytechnic University	CN201110208539(A) CN102895258(A)	Yes	-	Yes	Effect not recognised	Decision of rejection upheld
10	FS87391	F. Hoffmann-La Roche AG	CN200880022591(A) CN101687930(A)	Yes	-	Yes	Effect not recognised	Decision of rejection upheld
11	FS86137	Nicox S.A.	CN200880004081(A) CN101652380(A)	Yes	-	Yes	Effect not recognised	Decision of rejection upheld
12	FS77207	Reviva Pharmaceuticals, Inc.	CN201080019233(A) CN102413830(A)	Effect ①: No Effect ②: Yes	-	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: Not recognised	Decision of rejection upheld
13	FS130009	Boehringer Ingelheim Pharma GmbH & Co.KG	CN201410065809(A) CN104055778(A)	Yes	-	No	No	Decision of rejection upheld

14	FS126576	Artificial Cell Technologies, Inc.	CN201310173837(A) CN103357007(A)	Yes	-	No	No	Decision of rejection upheld
15	FS123914	Euro Euro Celtique SA	CN201310269906(A) CN103394090(A)	Yes	-	No	No	Decision of rejection upheld
16	FS123955	International Institute of Cancer Immunology, Inc.	CN201310009095(A) CN103103246(A)	Yes	-	No	No	Decision of rejection revoked after removal of the solution
17	FS123972	Merck & Co., Inc.; Istituto Di Ricerche Di Biologia Molecolare P. Angeletti Spa	CN200780048666(A) CN101611039(A)	Yes	-	No	No	Decision of rejection upheld
18	FS121933	Life Technologies Corporation	CN201180018980(A) CN103097547(A)	Yes	-	No	No	Decision of rejection revoked after removal of the solution

19	FS116396	Novartis A.G.	CN201210290408(A) CN102861332(A)	Yes	-	No	No	Decision of rejection upheld
20	FS73780	Celgene Corporation	CN200780042615(A) CN101535291(A)	Yes	-	No	No	Decision of rejection upheld
21	FS114965	AbbVie Biotechnology Ltd	CN201210239238(A) CN102755646(A)	Yes	-	No	No	Decision of rejection upheld
22	FS114794	Mitsubishi Tanabe Pharma Corporation	CN201210006859(A) CN102584799(A)	Yes	-	No	No	Decision of rejection upheld
23	FS113787	Novo Nordisk A/S	CN201180023303(A) CN102883743(A)	Yes	-	No	No	Decision of rejection upheld
24	FS112943	Morphochem Aktiengesellschaft für kombinatorische Chemie	CN200480038072(A) CN1898238(A)	Effect ①: Yes Effect ②: Yes	-	Effect ①: No Effect ②: No	Effect ①: No Effect ②: Technical effect not recognised	Decision of rejection upheld

25	FS112101	Teva Pharmaceutical Industries Ltd	CN201180040545(A) CN103038227(A)	Yes	-	No	No	Decision of rejection upheld
26	FS106209	Wyeth LLC	CN200980129758(A) CN102202667(A)	Yes	-	No	No	Decision of rejection upheld
27	FS106047	Biolab Sanus Farmaceutica Ltda.	CN201080038108(A) CN102625800(A)	Yes	-	No	No	Decision of rejection upheld
28	FS96928	L'Universite Montpelier II; Idenix Pharmaceuticals, Inc.; University of Cagliari; The Centre National de la Recherche Scientifique	CN201110253393(A) CN102424698(A)	Yes	-	No	No	Decision of rejection upheld
29	FS96776	Laboratoire M2	CN200980121508(A) CN102083307(A)	Yes	-	No	No	Decision of rejection upheld

30	FS89967	Health Research, Inc.	CN200880012072(A) CN101675066(A)	Yes	-	No	No	Decision of rejection upheld
31	FS87913	Cytochroma Inc.	CN200980112429(A) CN101998949(A)	Yes	-	No	Effect not recognised	Decision of rejection revoked after amendment
32	FS52756	Eisai R & D Management Co., Ltd.	CN200580023071(A) CN1984890(A)	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: -	Effect ①: No Effect ②: No	No	Decision of rejection upheld
33	FS85966	Novartis A.G.	CN200510072738(A) CN1733307(A)	Yes	-	No	Considered on the basis of Guidelines of 1993.[1]	Decision of rejection upheld
34	FS125512	FibroGen, Inc.	CN201310337398(A) CN103497184(A)	No	Yes	No	No	Decision of rejection upheld

[1] In respect of the case a reexamination decision was made earlier in which the Collegiate Panel did not accept the supplementary experimental data submitted by the applicant, who subsequently filed an administrative appeal with the Beijing Higher People's Court (BHPC). BHPC overturned said reexamination decision, and accordingly the Patent Reexamination Board (PRB) reissued a reexamination decision accepting the post-filing data in accordance with the final judgement made by BHPC.

35	FS119880	Boehringer Ingelheim International Gmbh	CN201310093566(A) CN103204903(A)	No	Yes	No	No	Decision of rejection upheld
36	FS96530	International Institute of Cancer Immunology, Inc.; Chugai Seiyaku Kabushiki Kaisha; Dainippon Sumitomo Pharma Co., Ltd.	CN200680051914(A) CN101336249(A)	No	Yes	No	No	Decision of rejection upheld
37	FS129717	Cadila Healthcare Limited	CN201280006760(A) CN103354757(A)	No	No	No	No	Decision of rejection upheld
38	FS127243	Endorecherche Inc.	CN201180039155(A) CN103037862(A)	No	No	No	No	Decision of rejection upheld
39	FS126730	Merck & Co., Inc.	CN201410039746(A) CN10372433	No	No	No	No	Decision of rejection upheld

			5(A)					
40	FS125319	Novartis A.G.	CN201210101874(A) CN102627658(A)	No	No	No	No	Decision of rejection upheld
41	FS124697	Tactical Therapeutics, Inc	CN201310005468(A) CN103251601(A)	No	No	No	No	Decision of rejection upheld
42	FS124264	Pfizer Inc.; Provectus Pharmaceuticals, Inc.	CN201280018290(A) CN103476943(A)	No	No	No	No	Decision of rejection upheld
43	FS123804	Abraxis BioScience, Inc.	CN201310233709(A) CN103285395(A)	No	No	No	No	Decision of rejection upheld
44	FS122196	L'Universite Montpelier II; Idenix Pharmaceuticals, Inc.; University of Cagliari; The Centre National de la	CN201310036638(A) CN103319554(A)	No	No	No	No	Decision of rejection upheld

		Recherche Scientifique						
45	FS115563	Exelixis, Inc.	CN201080012656(A) CN102388024(A)	No	No	No	No	Decision of rejection revoked after amendment
46	FS113303	The Board of Trustees of the Leland Stanford Junior University	CN201080030632(A) CN102459273(A)	No	No	No	No	Decision of rejection upheld
47	FS110935	Xigen Inflammation Ltd	CN200980130207(A) CN102112149(A)	No	No	No	No	Decision of rejection upheld
48	FS102364	Cornell University	CN200980112730(A) CN101998987(A)	No	No	No	No	Decision of rejection upheld

Appendix 2

Table 3 Rulings related to supplementary experimental data made by Beijing Intellectual Property Court (BIPC), Beijing Higher People's Court (BHPC), and Supreme People's Court of China (SPC) during the period between 2014 and 2017

No.	Judgment No.	Responsible court	Patentee	Whether the effect proved by supplementary experimental data is mentioned in the original description	Whether the effect proved by supplementary experimental data is deducible from the original description	Whether relevant data are disclosed in the original description	Whether supplementary experimental data are considered by court	Reasoning behind ruling
1	Gaoxingzhongzi 1127/2014	BHPC	Bristol-Myers Squibb Company; Zymogenetics, Inc.	Yes	-	No	No	Publication date of supplementary evidence subsequent to patent filing date
2	Gaoxingzhongzi 2364/2013	BHPC	Mitsubishi Tanabe Pharma Corporation	Yes	-	No	No	Supplementary evidence submitted after patent filing date and not

								disclosed in the original application
3	Xingtizi 8/2014	SPC	Warner-Lambert Company LLC	Yes	-	No	No	Not easily conceivable by a person skilled in the art
4	Gaoxingzhongzi 1244/2013	BHPC	Novartis A.G.	Yes	-	No	Yes[2]	Misapplication of law; Judgment to be reissued on the basis of the Guidelines of 1993
5	Jingzhixingchuzi 2069/2015	BIPC	Celgene Corporation	Yes	-	No	No	Technical effect unlikely to be reasonably expected
6	Gaoxingzhongzi 1184/2014	BHPC	Boehringer Ingelheim	Yes	-	No	No	Technical effect not

[2] This case is an appeal based on Reexamination Decision No. 48 of Table 1 in which the Beijing Higher People's Court (BHPC) reversed the first reexamination decision and subsequently the Patent Reexamination Board (PRB) reissued a reexamination decision on the basis of said final judgement made by BHPC.

			Pharma GmbH & Co.KG					disclosed in the description
7	Jingzhixingchuzi 3431/2015	BIPC	Boehringer Ingelheim Pharma GmbH & Co.KG	Yes	-	No	No	Technical effect unlikely to be reasonably expected
8	Jing73xingchuzi 2599/2016	BIPC	Boehringer Ingelheim Pharma GmbH & Co.KG	Yes	-	No	No	Technical effect unlikely to be reasonably expected
9	Jingxingzhong 3668/2017	BHPC	Boehringer Ingelheim Pharma GmbH & Co.KG	Yes	-	No	No	Technical effect unlikely to be reasonably expected
10	Gaoxingzhongzi 382/2014	BHPC	Otsuka Pharmaceutical Co., Ltd.	Yes	-	No	No	Technical effect unlikely to be reasonably expected
11	Jingzhixingchuzi 1599/2015	BIPC	Zhou Xingyuan et al.	Yes	-	No	No	Technical effect unlikely to be

								reasonably expected
12	Gaoxing(zhi)zhongzi 2305/2014	BHPC	Eisai R & D Management Co., Ltd.	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: -	Effect ①: No Effect ②: No	No	Technical effect unlikely to be reasonably expected
13	Jingzhixingchuzi 5395/2015	BIPC	Shandong Xinshidai Medicine Industry Co., Ltd.	No	No	No	No	Technical effect not disclosed in the description
14	Jingxingzhong 3046/2017	BHPC	Shandong Xinshidai Medicine Industry Co., Ltd.	No	No	No	No	Technical effect not disclosed in the description
15	Gaoxingzhongzi 309/2015	BHPC	Celgene Limited	No	No	No	No	Technical effect not disclosed in the description