# Supplementary Experimental Data and Inventive Step Assessment

Rui Songyan

In cases relating to assessment of inventive step, people in the IP circle have paid much attention to issues such as whether patent applicants or patentees are provided with an opportunity to supplement experimental data to prove the related technical effect of the invention, under what circumstances the supplementary experimental data are admitted, and how the admitted experimental data will affect the assessment of inventive step. In regard to these issues, this article makes the following analysis in conjunction with various situations in juridical practice from different perspectives.

## I. Legal basis and rationality analysis

The Guidelines for Patent Examination stipulate in Part II, Chapter Ten, Section 3.5 (On supplementary experimental data), Item 3.5.1 (Examination Principle) that "the examiner shall conduct examination on the experimental data supplemented after the filing date by the applicant for meeting the requirements of, e.g., Articles 22.3 and 26.3 of the Patent Law. The technical effect proved by the supplementary experimental data should be the one derived by those skilled in the art from the content disclosed in the patent application."

In pursuant of this provision, the examiner should not take no account of the supplementary experimental data simply because of no recitation in the description, but make a judgment on whether to accept and admit the supplementary experimental data on a case-by-case analysis instead. After all, the sufficiency of disclosure as required by the principle of disclosure in exchange for protection in the Patent Law is not defined to be as specific as experimental data. In the assessment of inventive step, the patentee cannot predict the closest prior art possibly compared in a specific case, and it is unreasonable to require the patentee to recite the difference in technical effect between the patent in suit and the prior art. Under such circumstances, if the patentee is not allowed to supplement experimental data, it will not only render it impossible for the patentee to prove the technical effect of the patent in suit over the closest prior art, thereby unreasonably damaging the patentee's interests, but also objectively increase the requirement for the sufficiency of disclosure of the description. In this sense, accepting and examining such experimental data is a must.

Nevertheless, not all supplementary experimental data can be accepted or admitted. In the light of the above provision of the Guidelines for Patent Examination, the technical effect proved by the admitted experimental data should be the one "derived" by those skilled in the art from the content disclosed in the patent application. It means that those skilled in the art can, by virtue of the content disclosed in the patent application or their cognitive capabilities, figure out the technical effect, as well as the fact that the technical effect is applicable to all the claimed technical solutions within the scope of the claims and relevant to the distinguishing technical feature. The supplementary experimental data that does not meet the above requirement should not, in principle, be accepted or admitted so as to prevent the patentee from obtaining a patent based on the undisclosed content; or otherwise, the principle of disclosure in exchange for protection is violated.

## II. Examination of supplementary experimental data

In the existing cases, the supplementary experimental data are manifested in a variety of forms, wherein the most common ones are experimental reports and appraisal reports. For instance, in the Enzalutamide case [1], the patentee submitted the appraisal report concerning the comparison between technical effects of the patent in suit and the Compound 41 (namely, the closest prior art). In some cas-

es, the parties concerned furnished the experimental records during the R&D process of the patent in suit. For instance, in the Empagliflozin case [2], the patentee filed relevant experimental data and diagrams. In addition to the above forms, the published documents of relevant patents are also used in some cases. For instance, in a case relating to a crystal form patent, [3] the experimental data supplemented by the patentee is the published patent documents concerning the parent compound of that crystal form. Moreover, the documents cited in the patent descriptions are also used as supplementary experimental data in some cases. For instance, in the Grace case [4], the supplementary experimental data was the Table 4-9 of the U.S. application cited in the description of the application in suit, wherein the compound IED1 corresponds to the compound 10 of the Reference 22 (i. e., the closest prior art), and the compounds IED2 to 12 respectively correspond to a plurality of compounds of the application in suit. Said Table provides data relating to catalytic activity and stereoselectivity, which is also the technical effect claimed by the patent applicant.

No matter which form the supplementary experimental data is presented in, the most important issue is to make sure whether the respective technical effects of the patent in suit and the closest prior art can be confirmed by the content of the supplementary experimental data. The following text will analyze the examination of supplementary experimental data from two perspectives: the confirmation of the technical effect of the patent in suit and the confirmation of the closest prior art.

1. Confirmation of the technical effect of the patent in suit

(1) No recitation of the technical effect in the description

As for the technical effect that is neither explicitly nor implicitly recited in the description, even if the supplementary experimental data can prove that the patentee has verified the technical effect prior to the filing date of the patent, the technical effect shall, in principle, not be taken into consideration in the assessment of inventive step, unless those skilled in the art are aware of the technical effect based on their knowledge of the prior art before the filing date thereof. Otherwise, the patentee may obtain the patent based on its undisclosed content, which violates the basic principle of disclosure in exchange for protection.

The Empagliflozin Case [5]

This case relates to an invention patent No. 201310414119.9 and entitled "Glucopyranosyl-Substituted Benzol Derivatives, Drugs Containing Said Compounds, the Use Thereof and Method for the Production Thereof", wherein claim 1 reads as follows:

"1. Glucopyranosyl-substituted benzene derivatives, selected from (2) 1-chloro-4-([β]-D-glucopyranos-1-yl)-2-[4-((R)-tetrahydrofuran-3-yloxy)-benzyl]-benzene, and (3) 1-chloro-4-([β]-D-glucopyranos-1-yl)-2-[4-((S)-tetrahydrofuran-3-yloxy)-benzyl]-benzene, or physiologically acceptable salts thereof."

The closest prior art cited in this case is Exhibit 1 (E1). The compound of E1 has an SGLT-2 inhibitory activity, and can treat or delay diabetes, etc. Though raising no objection to the above-mentioned technical effect of E1, the patentee deemed that in addition to the technical effect of E1, the patent in suit also has the high selectivity of SGLT-1, and supplemented experimental data to support such a technical effect.

Regarding the technical effect of high selectivity of SGLT-1, the patentee admitted the absence of explicit recitation of such a technical effect in the description, but asserted that it was implicitly recited in the object of the invention of the description as follows: "the aim of the present invention is to find new pyranosyloxy-substituted benzene derivatives, particularly those which have an activity with respect to theare active with regard to the sodium-dependent glucose cotransporter SGLT, particularly SGLT2. Another further aim ofpurpose of the present invention consists in demonstratingis to discover pyranosyloxy-substituted benzene derivatives which can be used in vitro and/or in vivo in comparison with known structurally similar compounds have an increased inhibitory effect on the sodium-dependent glucose cotransporter SGLT2 and/or have improved have an enhanced inhibitory effect on the sodium-dependent glucose cotransporter SGLT2 in vitro and/or in vivo compared with known, structurally similar compounds and/or have better pharmacological or pharmacokinetic properties." In this regard, the court held that in spite of the simple mention of SGLT and SGLT-2, the technical effect that SGLT-1 has a high selectivity was not implicitly disclosed in the context of the full description. Hence, the patentee's claim that the description implicitly discloses such a technical effect cannot be upheld.

Surely, the fact that such a technical effect is neither explicitly nor implicitly recited in the description does not mean that it cannot be taken into consideration in the assessment of inventive step. If those skilled in the art could recognize such a technical effect, it can also be used to de-

termine the technical problem actually solved. But in this case, the patentee clearly stated that those skilled in the art have no idea of such a technical effect. Based on this patentee's statement and in consideration of current evidence, the court held that since those skilled in the art are unable to know the technical effect based on the description and knowledge of the prior art of the patent in suit, even if the experimental data supplemented by the patentee can prove that the patent in suit has the high selectivity of SGLT-1 and such a technical effect has been verified by the patentee before the filing date, no consideration shall be given to the technical effect in the assessment of inventive step.

(2) Recitation of the technical effect in the description

Sufficiency of disclosure is one of the requirements for patent grant, which means that the description needs to recite the relevant technical effect of the claimed technical solution. In practice, the applicant may choose to supplement the technical effect with experimental data, or provide no experimental data at all. However, irrespective of the provision of the experimental data, as long as those skilled in the art can preliminarily identify the claimed technical effect of the patent in suit according to the description and by virtue of their cognitive capabilities, it shall be determined that the technical effect can be derived from the description. After all, it is improper to presume the content recited in the description to be untrue. Therefore, where the description recites the relevant technical effect, it shall be determined that the technical effect can be derived from the description unless there is counterevidence or sufficient reason to overturn it, and the patentee or patent applicant shall be allowed to supplement evidence to further prove the technical effect thereof.

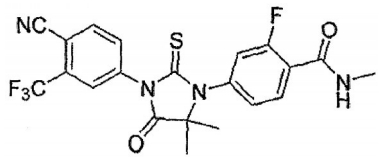
It shall be noted that the technical effect recited in the description shall correspond to "all" the technical solutions within the scope of protection of the subjected claims ; or otherwise, the relevant supplementary experimental data should not be accepted or admitted. Of course, overly strict standards should not be used for judging whether the technical effect corresponds to "all" the technical solutions. Generally speaking, even though the claims cover a broader scope of protection, thereby rendering it impossible to determine that all the technical solutions can achieve the relevant technical effect, patent applicants or patentees should be allowed to supplement experimental data for further proof unless it can be determined that some technical solutions cannot achieve relevant technical effects.

Whether the accepted supplementary experimental data can be admitted depends on whether the technical effect belongs to the technical contributions made by the applicant before the "filing date" of the disputed invention, and whether those skilled in the art can confirm the technical effect. As for the experimental data that meets the above requirements, the admission thereof will neither provide the applicants with protection that extends beyond their technical contributions, nor impair the public interests. Hence, the technical effects proved by the above experimental data are usually taken into consideration in the assessment of inventive step.

The Enzalutamide Case [6]

This case relates to an invention patent No. 200680025545.1 and entitled "Diarylhydantoin Compounds", wherein claim 1 reads as follows:

"1. A compound having the formula:




……"

This case relates to a compound patent. The description of the patent in suit recites that the compound has the technical effect of strong antagonistic activities with minimal agonistic activities against AR. However, the relevant specific content of the description (namely Figs. 21A and 21B) only involves the antagonistic effect, not the agonistic effect. As for the former, the description only provides a comparative bar chart, demonstrating the comparison between antagonistic effects under different situations, with no relevant specific data. Nevertheless, despite the technical effects recited in the description, the court still accepted and examined the experimental data supplemented by the patentee.

As for whether the supplementary experimental data should be considered, the court held that the supplementary experimental data was not a confirmation of strong antagonistic activities with minimal agonistic activities against AR that the patent in suit had before the filing date, and the description of the patent in suit provides the technical effect of the compound in *in vitro* experiments, whereas the experimental data supplemented by the patentee was to testify the effect of the compound on the tumor size in animal *in vitro* experiments. These two technical effects do not necessarily correspond to each other. Hence, the court did not

consider the technical effect claimed by the patentee in the assessment of inventive step.

The Crystal Form Patent Case [7]

This case relates to a patent application for invention No. 201410098658.0 and entitled "Processes for the Preparation of SGLT2 Inhibitors", wherein claim 6 reads as follows:

"6. A crystalline form of (2S, 3R, 4R, 5S, 6R)-2-(4-chloro-3-(4-(2-cyclopropoxyethoxy)benzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol, bis(L-proline) complex characterized by an X-ray powder diffraction pattern that comprises peak substantially according to Fig. 2."

In this case, the patent applicant claimed that the technical effect of claim 6 of the patent in suit is to selectively inhibit SGLT2, which is recited in the description but with no corresponding experimental data. The evidence supplemented by the patentee for proving the technical effect is Attachment 1, i.e., the published documents of PCT application WO2009026537A1 concerning the parent compound of the patent in suit, wherein the compound BQ is the parent compound of the complex in claim 6 of the patent in suit, and the data relating to the compound BQ in Table 2 shows that BQ has a selective inhibitory effect on SGLT2, to be specific, IC50 < 1μm.

The court admitted the experimental data recited in Attachment 1. The court held that the technical contribution made by claim 6 of the patent in suit is the crystal form, rather than the compound itself. The SGLT2 inhibiting effect as proved by the experimental data supplemented by the patent applicant is not the technical effect of the crystal form, but of the compound. Although there is no experimental data in the description to support the technical effect, in view that the technical effect is not the technical contributions as asserted in the description, whether the technical effect should be considered in the assessment of inventive step depends on whether Attachment 1 can prove that the technical effect is the technical contributions made by the patent applicant prior to the filing date of the application in suit, and whether the public can confirm the technical effect when knowing the relevant content of the application in suit.

Attachment 1 is the earlier patent application, and is also filed by the same applicant as that of the patent in suit. The compound BQ of the earlier patent application is the compound of the application in suit. As shown in the data relating to BQ in Table 2 of Attachment 1, BQ has a selective inhibitory effect on SGLT2, i.e., IC50 < 1μm. Therefore, although Attachment 1 is not the prior art of the application in suit, since Attachment 1 is filed by the same applicant as that of the patent in suit at a time earlier than the application in suit, it can prove that the patent applicant has testified the inhibitory effect of the compound of the application in suit on SGLT2 through experiments prior to the filing date of the application in suit, and the SGLT2 inhibiting effect as recited in the application in suit is not an assertion.

In addition, since the publication date of Attachment 1 is earlier than that of the application in suit, the public may have already known Attachment 1 when being informed of the application in suit, and confirm that the compound of the application in suit has the SGLT2 inhibiting effect. Thus, the acceptance of the experimental data presented in Attachment 1 will not impair the public interest. Accordingly, the court admitted the experimental data of Attachment 1 and decided to give consideration to the SGLT2 inhibiting effect in the assessment of inventive step.

The Cariprazine Case [8]

This case relates to an invention patent No. 200880015627.7 and entitled "Piperazine Salts as $D_3/D_2$ Antagonists", wherein claim 1 reads as follows:

"1. The crystalline trans 4-{2-[4-(2,3-dichlorophenyl)-piperazine-1-yl]-ethyl}-N,N- dimethylcarbamoyl-cyclohexylamine hydrochloride anhydrate having a powder X-ray diffraction pattern substantially as depicted in Fig. 3."

This case also relates to a crystal form patent. The CNIPA accepted the supplementary experimental data in the Decision on Invalidation and determined that claim 1 involves an inventive step because the crystalline form I of cariprazine monohydrochloride as compared with other salt forms demonstrates a high purity that is unexpectable by those skilled in the art. Regarding the technical effect concerning purity, although the court accepted the supplementary experimental data, it did not admit the technical effect proved thereby on the grounds that there is no evidence proving that the data was formed earlier than the filing date of the patent in suit.

As for the technical effect concerning a high purity, para. [0014] of the description of the patent in suit recites "the hydrochloride salt is particularly preferred, as it may be prepared in the highest yield and highest purity. Another advantage of the monohydrochloride salt is that it can readily be prepared using standard solvents and reaction conditions." Claim 1 of the patent in suit differs from the closest prior art E1 in that the compound 1 in E1 is cariprazine free

base, whereas claim 1 of the patent in suit seeks to protect the crystalline form I of cariprazine monohydrochloride, and the recitation of the purity effect in the description corresponds to the distinguishing technical feature. Thus, where those skilled in the art can preliminarily know, based on the above recitation, claim 1 of the patent in suit has the technical effect of purity improvement, the court also decided that the patentee can supplement the experimental data to further prove the technical effect although no data is provided in the description. Nevertheless, the relevant experimental data used for proving the above technical effect shall include the experimental data generated before the filing date of the patent in suit so as to avoid the breach of the first-to-file principle.

In this case, the experimental data supplemented by the patentee were Counter-Exhibits 1 and 2. Since the patentee admitted that Counter-Exhibits 1 and 2 do not show any specific time when the experiment was conducted and there is no other evidence proving that the patentee recognized the technical effect concerning purity before the filing date of the patent in suit, the court did not affirm said technical effect. On such a basis, as for the conclusions of the Decision on Invalidation that "the crystalline form I of cariprazine monohydrochloride of claim 1 of the patent in suit as compared with other salt forms demonstrates a high purity that is unexpectable by those skilled in the art", which was drawn on the basis of the above data, and that claim 1 of the patent in suit involves inventive step, the court deemed that they lacked factual support.

The Sorafenib Case [9]

This case relates to an invention patent No. 200680007187.1 and entitled "Pharmaceutical Composition Comprising an Omega-Carboxyaryl Substituted Diphenyl Urea for the Treatment of Cancer", wherein claim 1 reads as follows:

"1. A pharmaceutical composition which is a tablet comprising the p-toluenesulfonic acid salt of 4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-phenoxy}-pyridine-2-carboxylic acid methyl amide as the only active agent in a portion of at least 75% by weight of the composition and at least one pharmaceutically acceptable excipient, wherein the active agent is micronized, and the micronized form has a particle size of from 0.5 to 10μm; wherein the composition comprises a filler in a portion of from 3 to 20%, a disintegrant in a portion of from 5 to 12 %, a binder in a portion of from 0.5 to 8 %, a lubricant in a portion of from 0.2 to 0.8 % and a surfactant in a portion of from 0.1 to 2 % by weight of the composition; wherein microcrystalline cellulose is used as a filler, croscarmellose sodium is used as a disintegrant, hypromellose is used as a binder, magnesium stearate is used as a lubricant and sodium lauryl sulfate is used as a surfactant, and the composition is an immediate release tablet."

This case relates to a composition patent, and the experimental data supplemented by the patentee is aimed to prove the technical effects of immediate release and high hardness, which are cited in the description. As for the immediate release, the description recites "according to the present invention immediate release administration forms having a Q-value (30 minutes) of 75% due to USP-release method with device 2", and as for the hardness, "the tablet according to the invention shows for example a hardness of more than 80 N".

Although the above technical effects are recited in the description, since claim 1 provides several options for the drug loading efficiency of the active agent, whether the active agent is micronized, and all auxiliary materials and dosages, thereby making claim 1 have a broader scope of protection and a plurality of different technical solutions, the court cannot definitely ascertain that claim 1 of the present patent has the technical effects of immediate release and improved hardness according to the recitation of the description.

Nevertheless, the court still held that if the above technical effects are recited in the description, the patentee can supplement the experimental data to prove them. The experimental data supplemented by the patentee is E32 and E33, which are however to testify the effect of different auxiliary materials on the dissolution rate and hardness, rather than the technical effect of immediate release and improved hardness as asserted in the patent in suit. In view of this, the court did not find that claim 1 achieves the technical effect of immediate release and improved hardness after taking the supplementary experimental data into consideration.

(3) Technical effect and distinguishing technical feature(s)

In cases involving the assessment of inventive step, the parties concerned supplement the experimental data directly for the purpose of proving the technical effect, but indirectly for the sake of testifying the technical problem actually solved by the patent in suit over the closest prior art.

Since the technical problem is associated with the distinguishing technical feature(s), the recitation of the technical effect in the description should be linked with the distinguishing technical feature(s). This means that if those skilled in the art cannot know that a technical effect is associated with the distinguishing technical feature(s) based on the description or their cognitive capabilities, it can be presumed that the patentee has no knowledge of the relationship therebetween. Under such circumstances, the supplementary experimental data is generally not accepted. Otherwise, the scope of protection conferred may extend beyond the technical contributions made by the patentee.

Of course, the distinguishing technical feature(s) and the technical effect as recited in the description are not required to be in a cause-effect relationship, but should be associated with each other. After all, for a technical solution whose technical effect needs to be testified by experiments, the cause-effect relationship between the technical features and the technical effect can hardly be determined under some cases. As for the technical solution for which the cause-effect relationship between the technical effect and the distinguishing technical feature(s) can be proved, since the patent application documents play a role in reciting the technical solution and its technical effect that manifest the inventor(s)' creative work so that the public can carry out the relevant technical solution and get to know its technical effect, instead of defending against potential invalidation petition, there is no need to expound the correspondence between every technical feature and the technical effect.

But that is not to say that in the assessment of inventive step, as for the technical solution for which the cause-effect relationship between the technical effect and the distinguishing technical feature(s) can be proved, the patentee does not need to prove the cause-effect relationship therebetween, and the proof could be made by means of supplementing the experimental data. In the event that the description has already touched upon the association therebetween, the acceptance of the supplementary experimental data to further prove their cause-effect relationship will not provide the patentee with the scope of protection that extends beyond its creative work, and meanwhile will reduce the unnecessary burden on the patentee due to excessive requirements on the disclosure of the patent documents.

### The Nanjing Yoko Case [10]

This case relates to an invention patent No. 200910180610.3 and entitled "Method for Preparing Substituted Methylene Benzocyclodecene Ketoxime", wherein claim 1 reads as follows:

"1. A method for preparing a 5,6,7,8,9,10,11,12-octahydro-3-methoxy-5-methyl-5,11-methylenebenzocyclodecene-13-one oxime, comprising the steps of: (1) using 7-methoxy-1-methyl-2-tetralone as a starting material, in its toluene or xylene solution, and in the presence of a phase transfer catalyst and in an alkaline environment, to be subjected with 1,5-dibromopentane to an alkylation reaction to obtain 1-(5-bromopentyl)-7-methoxy-1-methyl-tetralone …… ; wherein …… the phase transfer catalyst described in step (1) is tetrabutylammonium bromide."

The closest prior art in this case is the technical solution of E3, which uses the catalyst N-(p-trifluoromethyl)benzyl cinchonidine bromide (B). It differs from the patent in suit in the catalyst, that is to say, the patent in suit uses the phase transfer catalyst, i.e., tetrabutylammonium bromide. The patentee claimed that the above distinguishing technical feature enabled the patent in suit to have the technical effect of improving the yield as compared with E3, and supplemented the Counter-Exhibit 4 as the supplementary experimental data to prove that the technical effect resulted from the distinguishing technical feature, i.e., tetrabutylammonium bromide.

Regarding the relationship between the technical effect and tetrabutylammonium bromide, para. [0004] of the description of the patent in suit recites "the present invention adopts a method for preparing ……, which improves the yield and reduces the cost", and para. [0012] of the description recites "in the preparation method of the present invention, the phase transfer catalyst is a quaternary ammonium salt, preferably selected from ……, most preferably, tetrabutylammonium bromide." As known from the above recitation, the patent in suit has the technical effect of improving the yield in comparison with the background art. One of the major distinguishing features therebetween is that the patent in suit adopts the phase transfer catalyst, and the distinguishing feature, i.e., tetrabutylammonium bromide, is the most preferably phase transfer catalyst. In addition, the parties concerned also recognize that the use of the phase transfer catalyst for improving the yield is the common knowledge. In view of all the above, it can be determined that tetrabutylammonium bromide is associated with yield improvement. Where the description recites the association between the distinguishing feature and the tech-

nical effect, the technical effect proved by the Counter-Exhibit 4 can be derived by those skilled in the art from the disclosure of the patent application. For this reason, the court accepted the Counter-Exhibit 4 as the supplementary experimental data.

The Antifoam Particles Case [11]

This case relates to a patent application for invention No. 201010182156.8 and entitled "Antifoam Particles", wherein claim 1 reads as follows:

"1. Antifoam particles (P), comprising: (A) a porous copolymer of urea, melamine, or a mixture thereof with an alkanal, and (B) a silicone antifoam composition which is liquid at 0° C, wherein……"

The application in suit relates to particles in detergents used to decrease foam produced during the laundering operation. The technical solution can be simply understood as including two components (A) and (B), wherein the component (B) functions to defoam, and the component (A) is a carrier to which the component (B) is attached. The application in suit merely differs from the closest prior art in that the component (B) (namely, defoamer) has a different structure. The patent applicant asserted that the application in suit has the following technical effects: 1. in comparison with other inorganic or organic carrier materials, the copolymer (A) of the application in suit absorbs the liquid silicone antifoam composition (B) very strongly; and 2. in comparison with starches preferably used as the carrier material of the silicone antifoam composition in the present field, antifoam particles comprising the copolymer (A) of the present application that serves as the carrier material surprisingly do not lose their foam-suppressing effect during storage. To prove the technical effects, the patent applicant supplemented the experimental data.

In this case, if the patent applicant's assertion is tenable, it means that the technical effects are associated with different defoamers, to be specific, two different defoamers (i.e., the distinguishing technical feature) need to be respectively mixed up with the same carrier material, the porous copolymer (A) (which is the carrier material of the two defoamers), so as to compare the technical effects achieved by the two mixtures, in such a way to know the technical effects generated by different defoamers. However, the specific technical effect recited in the description of the application in suit and the effect proved by the experimental data submitted by the patent applicant in the reexamination stage are both directed to the different technical effects of the mixtures formed by mixing the same defoamer "silicone antifoam composition (B)" (namely, the defoamer used in the application in suit) with different carrier materials, and these technical effects are apparently irrelevant to the distinguishing technical feature. Hence, even if the supplementary experimental data are taken into account, the technical effect as asserted by the patent applicant cannot be determined to be the technical problem actually solved by the application in suit.

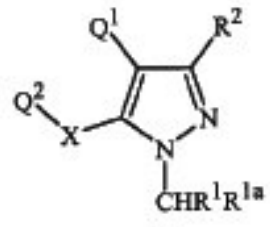
(4) Technical effect and the scope of protection of claims

The technical problem actually solved by the patent in suit over the closest prior art refers to the one actually solved by "all the technical solutions" falling within the scope of protection of the patent in suit with respect to the prior art. In this sense, the technical effect proved by the supplementary experimental data shall be applicable to all the technical solutions falling within the scope of protection of the patent in suit. The experimental data which is only applicable to a portion of technical solutions falling within the scope of protection of the patent in suit needn't be considered in the assessment of inventive step.

The FMC Case [12]

This case relates to a patent application for invention No. 201080019806.5 and entitled "Fungicidal Pyrazoles", wherein claim 1 reads as follows:

"1. A compound selected from Formula 1, N-oxides and salts thereof,



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wherein $Q^1$ is a phenyl ring optionally substituted with up to 5 substituents independently selected from $R^3$; $Q^2$ is a phenyl ring optionally substituted with up to 5 substituents independently selected from $R^3$; X is O, $NR^4$, or $CR^{15}R^{16}$; $R^1$ is H, halogen, $C_1$-$C_6$ alkyl, $C_1$-$C_6$ haloalkyl, $C_2$ – $C_4$ alkenyl, $C_2$ – $C_4$ alkynyl, $C_3$ – $C_7$ cycloalkyl, $CO_2R^5$, $C(O)NR^6R^7$, cyano, $C_1$ – $C_6$ alkoxy, $C_1$ – $C_6$ haloalkoxy, or $C_2$ – $C_5$ alkoxy alkyl; ……"

In this case, the patent applicant asserted that the application in suit has a better fungicidal activity with respect

to the compound 145 of Reference 4 serving as the closest prior art, with the supplementary experimental data submitted. It should be noted that the patent in suit contains a Markush claim, including a plurality of specific compounds within its scope of protection. However, the experimental data supplemented by the patent applicant only involves two of them. The patent applicant failed to furnish relevant experimental data for the rest specific compounds within the scope of protection of the patent in suit.

Under such circumstances, if the patent applicant deems that the technical effect verified by the supplementary experimental data is the technical problem actually solved by the patent in suit, it is quite necessary to prove or give a reasonable explanation for the technical effect which is applicable to all the specific compounds within the scope of protection of claim 1 of the application in suit. But in this case, no current evidence assisted in drawing such a conclusion, and the recitation in the description of the patent in suit even led to an opposite conclusion. As shown by the statistics in the description, although the compounds 53, 63, 260, 307 in Table A are specific compounds within the scope of protection of claim 1 of the patent in suit, their fungicidal activity is tested to be zero, which means that these specific compounds could in no way have a better technical effect as compared with the compound 145 of Reference 4. Accordingly, even if the supplemental experimental data is taken into consideration, it is impossible to prove that providing a better fungicidal activity is the technical problem actually solved by all the compounds of claim 1 of the application in suit.

The Grace Case [13]

This case relates to a patent application for invention No. 201510155006.0 and entitled "Production of Substituted Phenylene Aromatic Diesters", wherein claim 1 reads as follows:

"1. Ziegler-Natta procatalyst or catalyst compositions for the polymerization of olefin-based polymers, comprising substituted 1,2-phenylene aromatic diester compounds, at least one of which is selected from the compounds comprising: a substituted 1,2-phenylene aromatic diester selected from …… 1,2-naphthalene dibenzoate, 2,3 naphthalene dibenzoate……"

In this case, the patent applicant asserted that the application in suit had better catalytic activity and stereoselectivity, which was recited in Table 4-9 of the U.S. patent application recited in the description of the patent in suit, rather than the description of the patent in suit itself. Since the cited application was published subsequent to the priority date of the application in suit, which does not comply with the relevant provisions of the Guidelines for Patent Examination, the cited document cannot be regarded as a part of the description of the application in suit. Hence, the patent applicant asserted that the cited document should serve as the supplemental experimental data.

Both parties recognized that the compounds IED 2-12 in Table 4-9 correspond to those in the application in suit, and IED 1 corresponds to the compound 10 of Reference 22 (namely, the closest prior art). But it should be noted that the comparison of activity data in Table 4-9 shows that a portion of the compounds of the application in suit has better activity than the compound 10 of the closest prior art, while the other portion merely has an activity substantially the same as that of the compound 10. For instance, when the precursor is MagTi-1 and the amount of H2 is 1500, the activity of IED1 is 20.9 and that of IED4 is 19.3. The same goes for stereoselectivity (XS). For instance, when the precursor is SHACTM310 and EED is DCPCMS, the XS value of IED1 is 8.1 and that of IED7 is 8.63. The smaller the XS value, the better the stereoselectivity. Thus, IED1 has better stereoselectivity than IED7. It can be seen that the above data cannot prove that "all the compounds" falling within the scope of protection of the application in suit have a better technical effect than the compound 10 of Reference 22. In view of this, the cited document cannot prove that the application in suit has better activity and stereoselectivity than the compound 10.

2. Confirmation of the technical effect of the closest prior art

In cases concerning the supplementary experimental data, if the experimental data proves by means of comparing experiments that the patent or patent application in suit has a better technical effect over the closest prior art, the experimental data used for comparison should in principle correspond to the closest prior art. But there are also exceptions in practice. In a few cases, the technical solutions used for comparison by the parties concerned are those of documents other than the closest prior art. Under such circumstances, unless a reasonable explanation is provided, the comparative data cannot be taken as the basis for assessing the inventive step. Furthermore, it should be noted that during comparison, it must make sure that the technical solution used for comparison and that of the patent in suit

adopt substantially identical experimental conditions; or otherwise, the experimental results of the two are hard to be directly compared.

The FMC Case [14]

In the FMC Case as mentioned above, the closest prior art is the compound 145 of Reference 4. But in the experimental data supplemented by the patent applicant, what are compared with the application in suit are other two specific compounds of Reference 4 instead. Where the patent applicant recognized that the compound 145 of Reference 4 can be produced without offering reasonable explanation for why the compound 145 is not selected or providing counterevidence, the court held that such selection is not in line with common sense. Hence, the patent applicant's assertion that the application in suit has an unexpected technical effect over the compound 145 is untenable.

The Nanjing Yoko Case [15]

Things are different in the Nanjing Yoko Case as mentioned above. Although the experimental data supplemented by the patentee do not contain the catalyst in the closest prior art, the court still admitted the experimental data in view of the reasonable explanation made by the patentee.

The closest prior art in this case is the technical solution of E3, which uses the catalyst N-(p-trifluoromethyl)benzyl cinchonidine bromide (B). However, the technical solution compared in the experimental data (Counter-Exhibit 4) supplemented by the patentee is the technical solution of E3 that uses benzyltriethyl ammonium bromide (H). The patentee explained that the catalyst B was costly and difficult to obtain, which was not denied by the invalidation petitioner and the rationality of which was also recognized by the court. On this basis, as shown in the data in Table 1 of E3, the reaction 7 (to which the catalyst B applies) and the reaction 8 (to which the catalyst H applies) achieve substantially the same yield under the same reaction conditions with the only difference lying in the catalyst. It can be inferred therefrom that the difference between the yield using the catalyst B and that of the patent in suit is equal to the difference between the yield using the catalyst H in the Counter-Exhibit 4 and that of the patent in suit. Therefore, without any counterevidence, the court determined, on the basis of the Counter-Exhibit 4, that the patent in suit has the technical effect of significantly enhancing the yield over the closest prior art.

Moreover, the invalidation petitioner raised another objection to the Counter-Exhibit 4, namely, as compared with the experimental conditions recited in the description, the Counter-Exhibit 4 involves a proportional decrease in the inventory rating and an increase in experimental steps, so the technical effect proved thereby should not be admitted. In regard to this assertion, the court held that under normal circumstances, the proportional change in the inventory rating had no impact on the experiment result. As for the experimental steps, although the description does not record the experimental steps one by one, the Counter-Exhibit 4 has completely repeated all the steps recited in the description. Under such circumstances, the invalidation petitioner shall bear the burden of proof if it believes that the steps adopted in the Counter-Exhibit 4, which are not recited in the description, have an impact on the experiment. In the absence of evidence from the invalidation petitioner, the court did not support such an assertion.

The Grace Case [16]

In the Grace Case as mentioned above, the court held that even if the experimental data relating to catalytic activity and stereoselectivity in Table 4-9 of the U.S. application was considered, since both parties recognized that the experimental conditions for IED 2-12 (some specific compounds within the scope of protection of the application in suit) and IED 1 (the closest prior art) are not completely the same, the experimental results are usually not comparable. Even though the compounds IED 2-12 are much better than the compound IED 1 in terms of data, however, without evidence or reasonable explanation from the patent applicant, whether the data is different or not does not indicate which technical effect is better, and accordingly cannot be used to prove the technical problem actually solved by the patent in suit over the closest prior art.

The Fuji Case [17]

This case relates to an invention patent No. 201380035675.3 and entitled "4-[5-(pyridine-4-yl)-1H-1,2,4-triazole-3-yl]pyridine-2-carbonitrile crystalline polymorph and production method therefor", wherein claim 1 reads as follows:

"1. Type I crystals of 4-[5-(pyridin-4-yl)-1H-1,2,4-triazol-3-yl]pyridine-2-carbonitrile exhibiting characteristic peaks in powder X-ray diffractometry at diffraction angles 2θ of about 10.1°, 16.0°, 20.4°, 25.7°, and 26.7°."

Although this case involves a novelty matter, the rules followed are the same as some of those for the comparative experiment in the assessment of inventive step. In this case, the present patent is directed to a crystal form, and the closest prior art is Embodiment 3 in Attachment 2, which dis-

closes the steps for preparing the crystal form, though not the structure thereof. The invalidation petitioner furnished a judicial appraisal report, showing that the crystal form was obtained by following the processing steps of Embodiment 3 in Attachment 2, which are the same as the steps for preparing the crystal form of the patent in suit. The only difference therebetween lied in that the inventory rating of the raw material used for experiment was in a proportion of 1 to 10 to the inventory rating of Embodiment 3 in Attachment 2.

The patentee raised two objections in this regard: first, no existing evidence can prove that the compound used in Attachment 3 was obtained on the basis of Embodiment 2 in Attachment 2; and second, the inventory rating of the raw material used in the preparation process of Attachment 3 was only one tenth of the inventory rating used in Attachment 2. The court held that although the raw material used by the appraisal agency in Attachment 3 was provided by the invalidation petitioner, 1H-NMR (proton nuclear magnetic resonance spectroscopy) data confirmed that the raw material was the compound 5- (2-cyano-4-pyridyl) -3- (4-pyridyl) -1,2,4-triazole p-toluenesulfonate. In view of the fact that Embodiment 2 in Attachment 2 also prepared said compound and confirmed the compound using H-NMR (proton nuclear magnetic resonance spectroscopy), the court can determine, without any counterevidence, that the raw material used by the appraisal agency was the compound prepared by the method of Embodiment 2 in Attachment 2, which satisfied the requirement of Embodiment 3 in Attachment 2. Although the inventory rating provided by Embodiment 3 in Attachment 2 was not followed in the judicial appraisal process, since the appraisal agency reduced the amount of all the raw materials to one tenth in proportion, it substantially had no impact on the structure of the crystal form. Hence, in the absence of counterevidence and reasonable reasons from the patentee, the court confirmed the structure of the crystal form of the closest prior art based on Attachment 3.

## III. Conclusion

The supplementary experimental data shall be examined from two perspectives: confirmation of the technical effect of the patent in suit and confirmation of the technical effect of the closest prior art. As for the relevant technical effect of the patent in suit, if there is no explicit or implicit recitation in the description, the supplementary experimental data, though capable of proving the technical effect, shall in principle not be considered in the assessment of inventive step, unless those skilled in the art are able to know the technical effect based on their knowledge of the prior art of the patent. As for the relevant technical effect recited in the description, if those skilled in the art are able to know that the technical effect is associated with the distinguishing technical feature(s) and applicable to all the technical solutions within the scope of protection of the patent in suit based on the recitation in the description and their knowledge of the prior art, it can be determined that the technical effect can be derived from the description and the patentee or patent applicant should be allowed to supplement evidence to further prove its technical effect, unless there is counterevidence or sufficient reasons to doubt. If the supplementary experimental data can prove that the technical effect belongs to the technical contributions made by the patentee prior to the filing date of the patent in suit, the technical effect can be taken into account in the assessment of inventive step. As for the technical effect of the closest prior art, the supplementary experimental data used for comparison shall correspond to the closest prior art unless there is reasonable explanation given by the patentee. In addition, during comparison, it must make sure that the closest prior art and the patent in suit adopt the same experimental conditions. ■

The author: Judge of the Beijing Intellectual Property Court

[1] See the Administrative Judgment No. Jing73xingchu 5353/2019.

[2] See the Administrative Judgment No. Jing73xingchu 1097/2018.

[3] See the Administrative Judgment No. Jing73xingchu 2626/2018.

[4] See the Administrative Judgment No. Jing73xingchu 3236/2021.

[5] See supra note 2.

[6] See supra note 1.

[7] See supra note 3.

[8] See the Administrative Judgment No. Jing73xingchu 6015/2021.

[9] See the Administrative Judgment No. Jing73xingchu 10072/2021.

[10] See the Administrative Judgment No. Jing73xingchu 3169/2021.

[11] See the Administrative Judgment No. Jingzhixingchuzi 2527/2015.

[12] See the Administrative Judgment No. Jing73xingchu 10016/2020.

[13] See supra note 4.

[14] See supra note 12.

[15] See supra note 10.

[16] See supra note 4.

[17] See the Administrative Judgment No. Jing73xingchu 11429/2019.