Overview of and Comments on Patent Administrative Lawsuits Heard at Supreme People's Court in 2016 and 2017 (II)

Ren Xiaolan and Huang Qiang *

This article systematically looks into patent administrative lawsuits concluded at the Supreme People's Court in 2016 and 2017, with an aim of reviewing some typical cases regarding description, claims, patentable subject matters, practical applicability and amendments extending beyond the original disclosure. This article also makes brief comments on hot issues in patent examination in the chemical and pharmaceutical field.

I. Sufficiency of disclosure

In 2016 and 2017, there are altogether seven cases concerning sufficiency of disclosure, among which two are noteworthy. One discussed drafting errors in the description and sufficiency of disclosure, and the other discussed factors affecting the sufficiency of disclosure of a chemical product.

In the case No. Zuigaofaxingzai 94/2016¹, the patent in suit is directed to a rotary dobby and a weaving loom provided with such a dobby. The invalidation requestor challenged that parts (a) and (b) in the description are ambiguous. In the Invalidation Decision, the PRB held that the challenged patent satisfied the requirements of Article 26.3 of China's Patent Law, because those skilled in the art are able to carry out the invention based on the text parts of the description and drawings. The second-instance court disagreed, holding that the description has drafting errors in the aforesaid parts (a) and (b), and "As for few errors made during the drafting process, if those skilled in the art can, based on their own professional skills and in conjunction with the contents of the description, directly and unambiguously determine that the few errors are obviously clerical er-

rors, the patent should be deemed to comply with Article 26.3 of China's Patent Law. If, however, there are so many errors that those skilled in the art have to make great efforts or lots of corrections to carry out the patented technical solution, it means that the description of the patent has serious drafting mistakes and does not comply with Article 26.3 of China's Patent Law."

In this regard, the Supreme People's Court first explained that "the description is one of the documents that an applicant must submit with the State Intellectual Property Office (SIPO) for disclosing an invention or utility model, and shall include the following information: technical field, background art, summary of the invention, drawings, and detailed description of the preferred embodiments. The description shall clearly set forth the technical solution of the invention or utility model, describe in detail the embodiments for carrying out the invention or utility model, and adequately disclose the technical contents necessary for understanding and carrying out the invention or utility model, to such an extent that those skilled in the art can carry out the invention or utility model. However, the description should not be read literally or understood rigidly; rather, whether the description explains the technical solution in a

clear and complete manner and whether those skilled in the art can carry out the invention shall be judged from the perspective of those skilled in the art and in consideration of the text parts as well as the drawings of the description." In this case, the invalidation requestor argued that parts (a) and (b) lead to insufficient disclosure of the description. However, judging from the text parts and drawings of the description, "some sentences in the description of the present patent are indeed ambiguous, but they are mostly related to the background or prior arts. Those skilled in the art can understand the technical meaning of the ambiguous parts when reading the description, and therefore carry out the technical solution of the invention based on their understanding. In this regard, it is improper to take the number or severity of errors as criterion for sufficiency of disclosure and account shall be taken of whether those skilled in the art can understand the technical solution and carry it out."

The Supreme People's Court further emphasized: "the extent to which the disclosure of the description is clear and complete is in association with the level of readers. Whether the description of a patent is clear and complete, or whether the description contains errors, are both judged by those skilled in the art, instead of the general public. In the event that those skilled in the art can understand, find out and correct the errors while reading the description, especially when such kind of understanding and correction will not result in any change of the claimed technical solution, or even impairment of publicity and stability of claims, the unclear parts in the description should be understood as if it had been corrected. Otherwise, the benefits obtained by the patentees would be obviously not commensurate to their contributions to the society." Therefore, "under the principle of protecting and encouraging invention-creations, errors in the description of a granted patent can be understood as if they had been corrected. Meanwhile, it is also necessary to prevent patentees from abusing the rule. Errors shall be accurately defined, and the interests between patentees and the public shall be balanced, so as to conform to the Patent Law's legislative intent of encouraging invention - creations, and boosting scientific progress and economic and social development."

In the case No. Zhixingzi 352/2015², the patent in suit is directed to a novel compound, a pharmaceutically acceptable salt thereof and a method for preparing the same. The Re-examination Decision rejected the application on the grounds that the description failed to sufficiently disclose experimental data supporting the pharmaceutical use of said compound. The second - instance court split the claims into two solutions, namely "a novel compound and a preparing method thereof" and "a pharmaceutically acceptable salt of the novel compound and a preparing method thereof", deciding that for a novel compound and a preparing method thereof, as long as the description discloses the structure and preparation of the compound to such an extent that those skilled in the art can prepare the compound with that structure accordingly, the description meets the requirement of sufficiency of disclosure. The description shall not be deemed as insufficient simply because the description fails to disclose adequate experimental data on certain pharmaceutical effects or a specific use of the novel compound. However, as far as the pharmaceutically acceptable salt of the novel compound is concerned, if the description fails to provide evidence showing the pharmaceutical use of the salt, the description does not sufficiently disclose the salt.

The Supreme People's Court revoked the above decision for the following reasons: "first, as an industrial property, an invention patent should have industrial application value. Patent protection should not be granted to inventions, whose technical significance is still unknown or which have no positive effect. Second, whether the technical solution of an invention has an industrial application value must be judged in accordance with the description and in view of the prior art, namely, the patent description is crucial in deciding whether an invention has been substantially completed and is eligible for patent protection. Hence, the description should recite technical information on whether an invention has industrial application value and whether it has been substantially completed." The criteria for sufficient disclosure of chemical inventions in terms of identification, preparation and use as recited in Part II, Chapter 10 of the Guidelines for Patent Examination is in line with Article 26.3 of China's Patent Law, and has been followed for a long time in practice. "Finally, as regards inventions in the field of chemistry, the requirement for disclosure of the use and effect thereof is determined by the characteristics thereof. In most cases, it is usually hard to predict whether a chemical invention can be carried out and what use or effect it may have. People have to resort to experimental results to find out the answers. Thus, ... if those skilled in the art are unable, on the basis of the prior art, to predict whether a novel compound has the use and/or technical effect stated in the description, the description shall provide qualitative or quantitative experimental data so as to prove the use and/or effect."

In the case, the invention aims at providing a compound having an inhibitory activity against sodium-dependent glucose transporter (SGLT) (the structure of which is shown in the formula I). However, the description merely recites a number of compounds of formula I, as well as embodiments for preparing the same, but provides no data in relation to the inhibitory activity against SGLT or its blood glucose lowering effect of any specific compounds, or any qualitative/quantitative data in support of the biological activity and pharmaceutical use of the compound of formula I. The retrial requestor provided several prior-art documents; however, the prior art compounds are structurally different from the compounds of formula I. Thus, it cannot be concluded therefrom that the claimed compound has an inhibitory activity against SGLT insofar as, in the formula I, Ring B is a thiophene ring, Y is -CH2-, and the link (-X-) between Ring A and glucose is a single bond. Although several known SGLT inhibitor compounds have the structure shown in the formula II below, it cannot be concluded that any compound of the said structure has an inhibitory activity against SGLT. As a result, it cannot be expected on the basis of the prior art that the compound of formula I has the inhibitory activity, and the application in suit does not comply with Article 26.3 of the Patent Law.



II. Clarity of claims

Precisely defining the protection scope of a claim by clear and unambiguous expression is a requisite for the grant of patent. In the case No. Zuigaofaxingshen 3044/ 2016³, the patent in suit is directed to an anti-electromagnetic pollution garment, wherein "metal nets or films, which have the function of screen protection and are formed by metal filaments or metal powder with high permeability and without residual magnetism, are arranged in the material of the said garment". The issue is whether the expression "high permeability" makes the claim unclear. The Court

held that permeability, also called magnetic permeability, can be expressed in absolute and relative terms. Terms such as "initial permeability" and "maximum permeability" may also be used in different situations. "Different concepts have different meanings, and their calculation methods are also different. Permeability is not a constant but varies with the change of magnetic field strength. The description of the patent in suit does not clarify the term "permeability" used in the claimed technical solution refers to absolute permeability, relative permeability, or any other concepts. The description neither defines a specific range for the "high permeability", nor specifies conditions, such as magnetic field strength H, for measuring the permeability. It is hard for those skilled in the art to find out the accurate meaning of "high permeability" mentioned in the patent in suit by reading the description thereof. Although terms "high permeability" and "high magnetic permeability" are used in some prior art documents, the meaning of high permeability is still too broad to be determined in view of different technical fields and magnetic field strength." Hence, seeing that the evidence submitted by the retrial requestor cannot prove that those skilled in the art has a unanimous understanding of the meaning or scope of the term "high permeability", and the accurate meaning of "high permeability" used in the patent in suit cannot be determined according to the description thereof, the protection scope of the claim is unclear.

III. Whether claims are supported by the description

In 2016 and 2017, there were five cases involving whether claims are supported by the description. Specifically, the following issues were discussed: which technical problem serves as the basis at the time of judging the support issue; and how to judge the support issue when contradictions or inconsistencies exist in the description.

(I) Whether a claim is supported by the description shall be judged based on the technical problem as recited in the description

In the case No. Zuigaofaxingzai 19/2016⁴, the Court reiterated that "the claims shall be supported by the description" in Article 26.4 of China's Patent Law is "an important system safeguarding the balance of interests between right holders and the public, preventing patent rights from invading the public domain, and keeping a necessary space for

subsequent innovations". On that basis, "a claim shall be deemed as not 'supported by the description', if the protection scope of the said claim is too broad due to inclusion of a technical solution which is unable to solve the technical problem to be solved by the patent in suit or achieve the technical effect to be achieved and if those skilled in the art cannot reasonably identify and exclude the said technical solution according to the contents sufficiently disclosed in the description and the overall state of the prior art." To be specific, "the technical problem to be solved and technical effect to be achieved by the patent in suit can be determined in view of the background art and defects thereof recited in the description, the object of the invention, the technical problem to be solved and advantageous effects recited in the Summary of the Invention, as well as those in relation to the technical problem and advantageous effects recited in the Detailed Description of Preferred Embodiments."

Moreover, the Court held that " 'being supported by the description' mainly involves the mutual relationship between claims and the description. Accordingly, ... the technical problem to be solved and technical effect to be achieved by the patent in suit shall be determined according to the description itself. It is improper to determine the aforesaid technical problem based on the distinguishing features of a claim over the prior art and with reference to the relevant parts of the description because the above method is the method used to find out 'the technical problem actually solved' in the evaluation of inventive step. However, 'the technical problem actually solved' may be different from the technical problem to be solved, and therefore cannot be directly used as the basis for determining whether the claim is supported by the description." The Court further explains that: first, the purpose of re-determining the technical problem actually solved is to evaluate the inventive step of a claim, and specifically, to find out whether the prior art as a whole teaches to apply the distinguishing features to the closest prior art to solve its existing technical problem. This purpose is not in line with the legislative purpose of Article 26.4 of China's Patent Law. Second, the technical problem actually solved is determined according to the distinguishing features of the claim over the closest prior art. Identification of the closest prior art is rather relative and dynamic, since it greatly depends on evidence submitted by an invalidation requestor or search conducted by an examiner. The technical problem actually solved varies with the closest prior art, and thus, in many cases, it is different from the technical problem to be solved as indicated in the description. Third, whether a claim is inventive is not a premise in determining whether the claim is supported by the description. If inventive step is not argued, there is no need to determine the closest prior art and the technical problem actually solved.

(II) Whether a claim is supported by the description shall be judged on the basis of contents sufficiently disclosed in the description

In the case No. Zuigaofaxingzai 19/2016 5, the Court further explained the relationship between the support issue and sufficiency of disclosure. The Court held that "claims are generalizations from one or more embodiments recited in the description. Whether claims are supported by the description shall be judged on the basis of the technical contents sufficiently disclosed in the description. As regards the contents insufficiently disclosed, since those skilled in the art are unable to carry them out, they shall not be considered as the basis for judging the support issue." In this concern, "embodiments in a description are not sufficiently disclosed, when there are obvious conflicts among the embodiments, so that those skilled in the art will reasonably doubt the authenticity and objectivity of the embodiments and doubt whether the embodiments can solve the technical problem to be solved and achieve the technical effect to be achieved," and if that is the case, it is improper to take those insufficiently disclosed embodiments into consideration when judging the support issue. In the above mentioned case, the description recites three embodiments, among which the first and third are not sufficiently disclosed and thus not considered in judging whether claims 1 to 47 are supported by the description. The Supreme Court made a judgment on whether claims are supported by the description mainly based on the second embodiment and other relevant contents in the description.

(III) Whether those skilled in the art has reasonable doubt is the criterion for judging whether a generic concept is supported by the description

In the case No. Zuigaofaxingzai 86/2016⁶, the issue is whether generic terms in claims are supported by the description. Claim 1 of the patent in suit covers an isolated enzyme with glucoamylase activity, wherein the enzyme includes the full length sequence shown in SEQ ID NO: 7. Claim 6 limits the homology of enzyme that "the enzyme is at least 99% identical with the full length sequence shown in SEQ ID NO: 7 and has a pl below 3.5 determined by isoelectrical focusing". Claim 10 further limits the source of enzyme, namely the enzyme is derived from the filamentous fungus genus *Talaromyces*, wherein the filamentous fungus is a strain of T. emersonii. In its Invalidation Decision, the PRB partially maintained the validity of the patent on the basis of claim 10 and its dependent claims, holding that claim 10 is supported by the description, but claims 1 and 6 are not. The main reasons are as followings: as to claim 1, the amino acid sequence is added at one end or both ends with amino acid, which may cause the polypeptide sequence to change, thereby leading to the loss or changes of activities or function. As to claim 6, although it limits the enzyme by its homology and function, it is still possible that the change of amino acid may result in the changes of function or activities. On the contrary, claim 10 limits the source of enzyme to the same strain, and verifies with experiments that the function and activity of enzyme can be maintained.

The finding in the Invalidation Decision was finally upheld by the Supreme People's Court, which stated that "if the generalization of a claim makes those skilled in the art reasonably doubt that one or more specific terms or options included in the generic terms cannot solve the technical problem to be solved by the invention or utility model or achieve the same technical effects, then it shall be deemed that the claim is not supported by the description." In the case, "those skilled in the art generally believe that a species is the basic unit of a taxonomic rank. As regards some basic features, individuals of the same specifies show a high degree of similarity to each other. The genetic sequencing of certain enzyme encoded in the same species of fungi or the same strain of fungi is generally stable. Occasionally, very few variation sequences with a very high homology exist. Therefore, the enzymes encoded by the gene are either defined or extremely rare." In this case, dual limitations, namely 99% homologous and the source of species or strain, have narrowed down the protection scope of claims 10 and 11 to a very limited number of enzymes. In addition, these two claims also include limitation on the isoelectrical focusing and glucoamylase activity of enzyme defined in claim 6. In the event that embodiments 1 to 4 have verified that the SEQ ID NO: 7 has glucoamylase activity, claims 10 and 11 are supported by the description.

(IV) As to claims involving numerical ranges, it is required to explain or provide embodiments on values near the endpoint

In the case No. Zhixingzi 260/2015 7, the patent in suit is directed to a filament-like plasma reactor, wherein claims 2 to 4 limit the diameter range of discharge wires and the gap therebetween, as well as the gap between the wires and the electrode board in the reactor. The issue here is whether the claims with numerical ranges of the above three features, which are broader than those in the description, are supported by the description. The Court held that "in determining whether claims are supported by the description, the criterion should be whether those skilled in the art can reasonably obtain or derive the protection scope of claims based on the disclosure of the description". "For a utility model patent involving numerical ranges, when the numerical ranges in the description are narrower than those in claims, if those skilled in the art can reasonably obtain or derive the numerical ranges in the claims from the disclosure of the description, those claims are supported by the description." In the case, the scopes of claims 2 to 4 are obviously broader than those disclosed in the description. The description neither explains or explicates the numerical ranges in claim 2 to 4 in detail, nor discloses any embodiments near the endpoint values. It is hard for those skilled in the art to reasonably obtain or derive the numerical ranges in claims 2 to 4 based on the description. Therefore, claims 2 to 4 are not supported by the description.

IV. Patentable subject matters

Articles 2 and 25 of the Patent Law stipulate the provisions related to patentable subject matters. In 2016 and 2017, there were five cases concerning this issue, all of which were re-examination cases. The Supreme People's Court upheld the Re-examination Decisions in all cases.

In the case No. Zuigaofaxingshenzi 3553/2017⁸, claim 1 is directed to a resource integration management method. The PRB hold that such a solution does not comply with Article 2 of China's Patent Law. In the retrial, the retrial requestor argued that "the claim of the present application is directed to a commercial model, including commercial rules and methods, as well as technical features. It is a circular economy commercial model, which mutually benefits enterprises and consumers in a win-win manner. The problem to be solved is a technical problem, the means adopted is technical means, and the effect to be achieved is also technical effect." In response to the above arguments, the Court held that "resource integration and management is a methodology, which, by applying certain systemic rules, effectively manages the resource and distributes the value of a large-scale resource or a resource group consisting of various resources in the society in a working environment where the resource group is formed. What it aims to solve is the existing limitation of resource integration, that is, the management of social resources. The reasonable integration and allocation of social resources is not a technical problem in the sense of the Patent Law. In the claimed solution, none of the features, such as indicating members of social resources by using digital symbol sequence clusters in the form of a point card number, creating a value chain, or unifying configuration of resources and managing points on a resource management service platform, involve technical means. The effect to be achieved, i.e. resource integration, is not a technical effect." Hence, lower-level decision and judgments are correct in finding the subject matter of claim 1 non-patentable.

In the three cases No. Zhixingzi 44/2015, 45/2015 and 46/2015⁹, patent applications are directed to hybrid ripple carry digital engineering methods. The Court held that the subject matters of the claims are rules and methods for mental activities. To be specific, "rules and methods for mental activities are those governing people's thinking, expression, judgement and memorization. Since neither using any technical means or applying the laws of nature, nor solving any technical problem or producing any technical effect, said claim is not patentable. It is not only because such a claim does not constitute a technical solution in the sense of the Patent Law and thus fails to comply with Article 2.2 of China's Patent Law, but also because it is the situation set forth in Article 25.1(2)." The solution of claim 1 of the application in suit involves "a mathematical method based on a prescribed numeral system, which belongs to abstract rules and methods that govern people to conduct mathematical calculations. Said solution does not use technical means or apply the laws of nature to solve a technical problem and produce a corresponding technical effect, and therefore falls within the scope of rules and methods for mental activities"

In the case No. Zuigaofaxingshenzi 1000/2016¹⁰, claim 1 claims a method of transferring game playing information to users and revenue generated from users by using a system. The Court held that "said solution transfers information and establishes a system by using current computer devices and Internet. A mobile device used by a user communicates with a game server through a digital mobile data network.....The problem to be solved is how a game provider generate revenue from providing online games. This "problem" is not a technical problem found in the prior art, but a result that a game provider generates revenue from users using a gaming system achieved under the rules set according to subjective wills. Thus, the problem to be solved by the application is not a technical problem." Meanwhile, "the means used are man-made rules for activities, under which information is exchanged, but the rules are set according to subjective wills and not restricted by the laws of nature. Although the system of claim 1 uses technical terms in the fields of computer or network, such as 'game server', 'billing server', 'digital mobile data network' and 'mobile device', it does not find or solve any technical problem existing in the internal structure of the current devices, or make an improvement to the performance of the devices, or cause any technical change to the constitution or function of the devices. Instead, it transfers information under the man-made interaction rules, without adopting any technical means. The achieved effect is merely related to a commercial management and control effect that generates revenue from a gaming system provided by an Internet service provider or wireless network provider, and should not be regarded as a technical effect." Since the solution claimed in claim 1 solves no technical problem, adopts no technical means and achieves no technical effect, it is not a patentable subject matter.

V. Practical applicability

In 2016 and 2017, there were five cases concerning practical applicability, all of which were re-examination cases. In the case No. Zuigaofaxingshenzi 789/2016¹¹, the Court held that "the practical applicability of an application shall be judged, based on the overall disclosure of the description and claims, whether the technical solution solves a technical problem and whether the said solution can be manufactured or used in industry." According to the description, the energy that maintains the rotational force mainly comes from "magnetic energy". In this invention, magnetic energy is used to provide a driving force by means of a special structure under the principle that unlike polarities attract each other and like polarities repel. In view of the description and observations made by the patent applicant, the Court analysed that "the source of the 'magnetic

ic energy' is a special internal structure of the power machine, and the 'magnetic energy' is also the main energy that keeps the power machine in rotation. However, it is wellknown that the inertia of a flywheel is provided by an external force. After an external force acts on the flywheel, it must, on the one hand, overcome the resistance and, on the other hand, accelerate an external rotor to make it rotate and do work. Additionally, keeping the magnetic field as a dynamic magnetic field also requires energy input. It can thus be seen that input energy has to be greater than output energy so as to keep pushing the flywheel forward and doing work externally. However, in accordance with the overall technical contents disclosed in the claims and description, the core of the claimed technical solution is to obtain 'magnetic energy' by means of the particular structure of the power machine in the event that the magnetic-suspension magnetic energy power machine only needs a small amount of direct current input to keep the flywheel in rotation, so as to achieve the technical effect of consuming no energy for continuous operation." Obviously, "since the device needs energy for operation, with only a small amount of kinetic energy as input, it is impossible to produce output energy larger than the input by means of the magnetic force generated in the magnetic field, let alone to keep the flywheel continuously rotating. The technical solution of the present application violates the law of conservation of energy." It "is merely an imagination or somewhat a result, and the technical solution of keeping the flywheel operating with the 'magnetic energy' cannot be manufactured or used in industry."

In the case, the Court also explained the relationship between practical applicability and sufficiency of disclosure, holding that the criterion that "a technical solution can be carried out" as required in Article 26.3 of China's Patent Law is different from the practical applicability requirement of "being able to be manufactured or used". "Being able to be manufactured or used" "means that it is possible for the technical solution of an invention or utility model to be manufactured or used in industry. If a technical solution violates the laws of nature, it cannot be applied, and thus cannot be manufactured or used in industry, let alone bring positive effects. In this sense, it does not matter whether relevant specific information is disclosed in the description or not." In the case, the description fails to disclose the specific technical solution that during the rotation of the flywheel, the rotor is energized at a "dead point" where a maximum resistance exists so as to ensure its movement in a correct direction. The description has a formal defect that the invention is not clearly and completely described to such an extent that those skilled in the art can carry it out, but it is not improper for the appealed Decision to make comments on lack of practical applicability in the presence of the substantive defect of the application.

VI. Amendments to application documents/patent documents

As for amendments to application documents/patent documents, two issues are usually faced in practice: the substantial one is whether amendments extend beyond the scope of the disclosure of the original application documents; and the procedural one is whether the timing and manner of amendments comply with the relevant laws and regulations.

There has been an obvious declination in the number of cases involving amendments extending beyond the scope of the original disclosure in recent years. In the case No. Zuigaofaxingshenzi 5586/2017¹², one of the issues is whether the amendments to claim 3 and the description extended beyond the scope of the original disclosure. The Court upheld the Re-examination Decision in its conclusion, but also emphasized that, regarding the examination criterion in Article 33 of China's Patent Law, "the scope of disclosure of the original description and claims should include the followings: contents explicitly expressed in the original description, drawings and claims, in words or figures; and contents that can be directly and definitely derived by those skilled in the art from the original description, drawings and claims. If, compared with the above contents, the patent application document does not introduce new technical contents after amendment, it can be determined that the amendments to the patent application documents do not extend beyond the scope of disclosure contained in the original description and claims." The expression "directly and definitely derived" is used to define the latter contents, which are different from the examination criterion of Article 33 as stipulated in the Guidelines for Patent Examination.

It is very rare to see cases involving the timing and manner of amendments. After the case No. Zhixingzi 17/ 2011 ¹³, the case No. Zuigaofaxingzai 41/2016 ¹⁴ concluded at the end of 2017 also involved the manner of amendments in the invalidation proceedings. The claim of the patent in

suit is directed to a method for preparing a pharmaceutical compound for treatment or prevention of hypertension, wherein the compound is "a compound of formula (I) or pharmaceutically acceptable salts or esters thereof", and the compound of formula (I) includes seven substituents R¹- R^{7} at key positions. In the invalidation proceedings, the patentee made two amendments: one is to delete the term "or esters" so that only "a compound of formula (I) or pharmaceutically acceptable salts thereof" remains; and the other is to selectively delete "C1-6 alkyl" from the group represented by R⁴, and a plurality of substituents from the group represented by R⁵. The Invalidation Decision accepted the first deletion, but rejected the second as it was not the deletion of a parallel technical solution. In this regard, the first-instance court upheld the Invalidation Decision, but the second-instance court opined differently that a Markush claim such as the claim in this patent, should be regarded as "a collection of a plurality of technical solutions", rather than "an entire technical solution".

The Supreme People's Court first clarified, in the judgment, the definition and characteristics of a Markush claim, holding that a Markush claim is "a generalized claim defined by a number of alternative elements." It is drafted in such a manner to solve the problem of lack of common generic term for multiple substituent groups in the field of chemistry. Hence, "for the sake of fairness, a Markush claim should be strictly interpreted. Irrespective of the number of variants and combinations, a Markush claim should be regarded as a generalized and combined solutionA Markush claim should be viewed as a collection of Markush elements, not various compounds. A Markush element can be a single compound, but only under particular circumstances. Generally speaking, a Markush element should be understood as a class of compounds having common properties and functions."

In view of the above characteristics of a Markush claim, the speciality of the invention in the field of chemistry, and that "patent applicant when drafting a Markush claim would have opportunity to write all structures into one claim so as to gain a scope of protection as broad as possible", amendments to a Markush claim in the invalidation proceedings must be strictly restricted. Amendments to a Markush claim can only be accepted under the principle that neither a class of compounds nor a single compound with new properties and functions is generated as a result of amendment. Surely, it also needs to be judged on a case-by-case basis. If a patent applicant or patentee is allowed to delete any option in any variant, even when such deletion narrows down the protection scope of a claim and does not impair the rights and interests of the public, since it is uncertain whether a new protection scope may be re-defined, the deletion will make the public unable to have a stable expectation and thus harm the stability of the patent system. The second - instance court obviously erred in determining a Markush claim as a collection of parallel technical solutions.

VII. Brief comments

In view of the overall situation of patent administrative litigations, and re-examination and invalidation cases in the past two years, considering China's innovation-driven development strategy and key industry policies in the 13th Five -Year Plan, it is expected that, over the next few years, disputes will increase in the following two fields: computer and information technology; and chemistry, pharmacy and biotechnology. Here we would like to make brief comments on the latter.

(I) Disputes over Markush claims will continue.

In the case No. Zuigaofaxingzai 41/2016, the Supreme People's Court clarified the characteristics of Markush claims and regulated the amendments to Markush claims in invalidation proceedings. It seems that the tug of war for Markush claims has come to an end. Frankly speaking, the judgment is only made from the perspective of fairness. Although, at the practice level, suggestions are given as to the amendments to patent documents in the invalidation proceedings, fundamental problems concerning Markush claims still remain. For instance, how can we logically explain the conflict that, on one hand, substituents in Markush claims can be selectively deleted during patent prosecution; on the other hand, a Markush claim is regarded as an entire technical solution in the invalidation proceedings and the deletion of substituents is strictly restricted? Moreover, in the case, the Supreme People's Court clarified "amendments to a Markush claim can only be accepted under the principle that neither a class of compounds nor a single compound with new properties and functions is generated as a result of amendment". Then, the problem here is how can we judge whether "a class of compounds or a single compound" possesses new properties or functions?

As for the first issue, we totally agree with the opinion of the Supreme People's Court in the case No. Zuigaofaxingzai 41/2016. At present, a Markush claim, as a drafting method, has deviated far away from its original purpose, and becomes a tool of applicants for pre-emptively claiming a protection scope as broad as possible. In practice, a very general formula structure with plenty of substituents and alternatives is very common. Even for an application with hundreds of synthetic embodiments, the scope defined by the claims is usually too broad to be commensurate with their contribution to the prior art. Concerning compounds with the same use, one applicant or different competitors file numerous applications in which the compounds are always defined by a generic Markush structure. This type of claims usually lead to overlapping scopes of related or similar applications. When priority, novelty or inventive step issues are further involved, what faces practitioners is a thickly-knitted net. The main reason for this awkward situation is that applicants use Markush claims as a "word game" rather than a drafting method to make the claims simple and clear. This trend is not in line with the purpose of patent system and should not be encouraged. However, if Markush claims are considered as entire technical solutions without exception, and no deletion is allowed during prosecution, it may go to another extremes. Although it seems logically contradictory to examine Markush claims differently during prosecution and in the invalidation proceedings, it is necessary to cnduct examination under uniform standards in current practice.

As for the second issue, we think it can be discussed in two different situations: the amended claim covers "a class of compounds", and the amended claim covers "a single compound". "A class of compounds" should be subdivided on the basis of the claim itself. For instance, "X compound or salts, esters and nitrogen oxides thereof" can be amended to "X compound", "salts of X compound", "esters of X compound" and "nitrogen oxides of X compound". "A single compound" must be a specific compound explicitly recited in the original application documents, including a compound disclosed in the embodiments. If the amended claim seeks to protect a compound not recited in the original application documents, the amendment may not comply with Article 33 of the Patent Law. If a compound has been explicitly disclosed in the embodiments of the original application documents, theoretically speaking, the amended claim may still be suspected of introducing the said compound, which was originally disclosed in the description but not claimed as a dependent

claim, into the protection scope through post-grant amendment. But fairly speaking, such a compound is the contribution made by the patentee to the prior art.

(II) Disputes over experimental data will continue.

As for inventions in the field of chemistry, main disputes over experimental data are: first, whether it is necessary to disclose experimental data in the application documents, or whether the experimental data disclosed in the application documents are sufficient to judge whether an application can be granted; and second, whether experimental data supplemented after the filing of an application should be accepted.

In response, the Supreme People's Court has established a logical system through a series of cases in recent years. Firstly, when a new chemical product is claimed, sufficient disclosure of the structure and preparing method thereof in the description is a precondition for obtaining patent protection for the chemical product ¹⁵. Meanwhile, if those skilled in the art cannot predict what use/effect the claimed chemical product has based on the prior art, providing gualitative or guantitative experimental data in the description to show certain use/effect is one of the necessary conditions for patent protection of the chemical product. ¹⁶ The gualitative or guantitative experimental data need to be disclosed to an extent that those skilled in the art are "convinced", and it seems that such a generic expression as "IC50 in the compound of the invention is..." cannot meet that requirement ¹⁷.

Second, any patent applicant or patentee can supplement experimental data, during prosecution or even in litigation, as evidence to prove that a technical solution has been sufficiently disclosed or a claim is inventive. However, on the one hand, the experimental conditions and methods used in the evidence must be strictly examined. The bottom line is that only conditions or methods, prior to the filing date (or priority date), those skilled in the art can directly obtain or readily envisage by reading the description are acceptable. ¹⁸ On the other hand, what the experimental evidence proves also needs to be strictly examined. Experimental evidence cannot be used to prove those that are not recited in the application documents submitted on the filing date, unless it is used to prove common knowledge or the knowledge and skills of those skilled in the art prior to the filing date ¹⁹. To be specific, if experimental evidence is used to prove the use/effect that is not explicitly recited in the original application documents, the experimental evidence

cannot be accepted ²⁰.

This logical system is consistent with current examination practice. We also agree with it. Nevertheless, in the following situations, disputes concerning experimental data still cannot be solved through this logical system.

In practice, fabricated experimental data or even technical solutions are found in some applications. Judging from a single application, the data are complete and have no defects. But if multiple applications of the same applicant are put together for comparison, it can be found that they are contradictory to each other and in violation of the R&D laws. Since the principle of good faith has not been introduced in the patent law, and investigative authority and capacity during patent prosecution, as an administrative procedure, is rather limited, the above logical system is really weak in dealing with such problems.

Another situation is that the original application documents explicitly recite that the invention aims to make improvements in a certain aspect, but fails to provide any qualitative or quantitative data to prove the improved effects. During the examination, the applicant supplemented corresponding experimental data and original experimental records, showing that experiments had been completed prior to the filing date and achieved experimental effects. If the experimental evidence is not accepted, the patent right cannot be granted for the invention. However, as the patent/ application has been disclosed, no one can obtain a patent for the same invention. Under such circumstances, the above logical system seems to be helpless in balancing the "first-to-file" rule and "protection of invention".

To conclude, although reality is richer than imagination, systematic review of precedents will definitely contribute to accurate application of law in practice.

The authors: Ren Xiaolan, Director of Chemical Appeal Division of the PRB; and Huang Qiang, Deputy Director of General Office of Jiangsu Examination Cooperation Centre of the SIPO

* All authors contribute equally to this article.

¹ An invention patent (No.97123476.0). The Invalidation Decision No. WX17561 upheld the validity of the patent. The First-instance Judgment No. Yizhongzhixingchuzi 1703/2012 upheld the Invalidation Decision; and the Second-instance Judgment No. Gaoxingzhongzi 991/ 2013 revoked the First-instance Judgment and the Invalidation Decision. The patentee filed a request for retrial and the Supreme People's Court revoked the Second-instance Judgment and upheld the Invalidation Decision.

² A patent application for invention (No. 200480022007.8). The Re-examination Decision No. FS47530. The First-instance Judgment No. Yizhongzhixingchuzi 1356/2013 upheld the Re - examination Decision; and the Second-instance Judgment No. Gaoxingzhongzi 2364/2013 upheld the First - instance Judgment and the Re - examination Decision with a part thereof rectified. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

³ A patent application for utility model (No. 200420091540.7). The Invalidation Decision No. WX23742 declared the patent wholly invalid. The First - instance Judgment No. Jingzhixingchuzi 23/2014 and the Second - instance Judgment No. Gaoxing(zhi)zhongzi 1549/2015 both upheld the Invalidation Decision. The patentee filed a request for retrial and the Supreme People's Court ruled to reject the request.

⁴ An invention patent (No.97197519.1). The Invalidation Decision No. WX18161 declared the patent partially invalid. The First - instance Judgment No. Yizhongzhixingchuzi 2111/2012 and the Second - instance Judgment No. Gaoxingzhongzi 961/2013 both upheld the Invalidation Decision. The patentee filed a request for retrial and the Supreme People's Court partially revoked and partially upheld the Invalidation Decision.

⁵ Ibid.

⁶ An invention patent (No. 98813338.5). The Invalidation Decision No. WX17956 declared the patent partially invalid. The First - instance Judgment No. Yizhongzhixingchuzi 2722/2012 and the Second - instance Judgment No. Gaoxing(zhi)zhongzi 3523/2014 both revoked the Invalidation Decision. The PRB filed a request for retrial and the Supreme People's Court revoked the First-instance Judgment and Second-instance Judgment, and upheld the Invalidation Decision.

⁷ A utility model patent (No. 200320109396.0). The Invalidation Decision No. WX19372 upheld the validity of the patent. The First-instance Judgment No. Yizhongzhixingchuzi 697/2013 upheld the Invalidation Decision; and the Second - instance Judgment No. Gaoxingzhongzi 1386/2013 revoked the First-instance Judgment and the Invalidation Decision. The PRB filed a request for retrial and the Supreme People's Court revoked the First-instance Judgment and Second-instance Judgment, and upheld the Invalidation Decision.

⁸ A patent application for invention (No. 200610157287.4). The Re-examination Decision No. FS65730. The First-instance Judgment No. Yizhongxing(zhi)chuzi 8600/2014 and the Second - instance Judgment No. Jingxingzhongzi 4655/2016 both upheld the Re-examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request. ⁹ The case No. Zhixingzi 44/2015 relates to a patent application for invention (No. 200610126077.9). The Re - examination Decision No. FS22807. The First-instance Judgment No. Yizhongzhixingchuzi 2142/ 2010 and the Second - instance Judgment No. Gaoxingzhongzi 134/ 2011 both upheld the Re - examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

The case No. Zhixingzi 45/2015 relates to a patent application for invention (No. 200510119817.1). The Re - examination Decision No. FS25606. The First-instance Judgment No. Yizhongzhixingchuzi 3411/ 2010 and the Second - instance Judgment No. Gaoxingzhongzi 139/ 2011 both upheld the Re - examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

The case No. Zhixingzi 46/2015 relates to a patent application for invention (No. 200510113953.X). The Re - examination Decision No. FS15117. The First-instance Judgment No. Yizhongzhixingchuzi 2405/2010 and the Second - instance Judgment No. Gaoxingzhongzi 144/2011 both upheld the Re - examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

¹⁰ A patent application for invention (No. 200710196739.4). The Re-examination Decision No. FS51365. The First-instance Judgment No. Yizhongzhixingchuzi 1910/2013 and the Second-instance Judgment No. Gaoxingzhongzi 1555/2014 both upheld the Re-examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

¹¹ A patent application for invention (No. 201010147700.5). The Re-examination Decision No. FS68294. The First-instance Judgment No. Yizhongxing(zhi)chuzi 10512/2014 and the Second - instance Judgment No. Gaoxingzhizhongzi 2084/2015 both upheld the Re - examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

¹² A patent application for invention (No. 201110319747.X). The Reexamination Decision No. FS87365. The First-instance Judgment No. Jingzhixingchuzi 4457/2015 and the Second-instance Judgment No. Jingxingzhongzi 5355/2016 both upheld the Re-examination Decision. The patent applicant filed a request for retrial and the Supreme People's Court ruled to reject the request.

¹³ An invention patent (No. 03150996.7). The Invalidation Decision No. WX14275 declared the patent wholly invalid. The First-instance Judgment No. Yizhongzhixingchuzi 1364/2010 upheld the Invalidation Decision, and the Second-instance Judgment No. Gaoxingzhongzi 1022/2010 revoked the First-instance Judgment and the Invalidation Decision. The PRB filed a request for retrial and the Supreme Peo-

ple's Court ruled to reject the request.

¹⁴ An invention patent (No. 97126347.7). The Invalidation Decision No. WX16266. The First-instance Judgment No. Yizhongzhixingchuzi 2403/2011 upheld the Invalidation Decision, and the Second-instance Judgment No. Gaoxingzhongzi 833/2012 revoked the First-instance Judgment and the Invalidation Decision. The PRB filed a request for retrial and the Supreme People's Court revoked the Second-instance Judgment, and upheld the First-instance Judgment and the Invalidation Decision.

¹⁵ The Administrative Judgment No. Xingtizi 8/2014.

¹⁶ The Administrative Ruling No. Zhixingzi 352/2015.

¹⁷ The Administrative Ruling No. Zhixingzi 340/2015, and the Administrative Ruling No. Zhixingzi 342/2015.

¹⁸ See supra note 15.

¹⁹ The Administrative Ruling No. Zhixingzi 77/2013.

²⁰ The Administrative Ruling No. Zhixingzi 41/2012, and the Administrative Ruling No. Zhixingzi 86/2011.