Examination and System Design in Relation to Amendment Going beyond Scope of Disclosure:

Thoughts from Supreme People's Court's Judgments Made in Two Administrative Cases

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The present study starts from two administrative patent cases the Supreme People's Court adjudicated in 2011 involving application of Article 33 of the Patent Law, and presents the various views arising from the adjudication, pondering on the issues that require our attention in the examination procedure of the cases *per se*, and analysing the impact of the cases on the patent system design.

It is common for an applicant to make amendment to his patent application in the practice of examination. The Patent Law, the Implementing Regulations of the Patent Law and the Guidelines for Patent Examination all have set forth detailed provisions regarding limitation on the amendment. To date, however, applicants, patent attorneys, examiners and judges hold considerably divided views on how to understand and implement these provisions. While many decisions the Patent Reexamination Board (PRB) made in many cases have been accepted in the judicial review, different voices have been heard in recent years. This article will present a brief analysis of the views arising from the application of Article 33 of the Patent Law by taking for example the two patent administrative cases the Supreme People's Court heard in 2011 involving the application of Article 33 of the Patent Law[1].

I. Brief of the cases

Case 1: Jiangsu Xiansheng medicament case

The case involved the application (03150996.7) for a patent for the invention relating to composite preparation of amlodipine and irbesartan. In the original text of the application, the two components are at the ratio of amlodipine: irbesartan=1:10-50. In the course of substantive examination, the applicant changed said ratio into 1:10-30. During the invalidation proceedings, the patentee amended the ratio of 1:10-30 into that of 1:30. The PRB refused to accept the amendment, and declared the whole patent invalid on the ground that the claim was contrary to Article 26, paragraph four, of

the Patent Law in the invalidation decision No. 14275 (the invalidation decision for short).

The trial court upheld the invalidation decision, and the court of appeal revoked or reversed it. Dissatisfied with the appellant judgment, the PRB requested the Supreme People's Court to retry the case. Upon retrial, the Supreme People's Court ruled to have maintained the Appellant Judgment (the Administrative Decision No. Zhixing 17/2011) (Judgment No.17 for short).

Issue 1: Whether amendment of 1:10-50 into 1:30 went beyond the initial scope of disclosure

It was noted in the invalidation decision that the ratio 1:30 was not clearly recorded in the original claims and description, namely the amendment went beyond the initial scope of disclosure.

It was concluded in Judgment No.17 that the ratio 1:30 had been recorded in the description, and the amendment had not gone beyond the scope of disclosure contained in the original application on the following grounds:

(1) The description disclosed the composition of amlodipine 1mg and irbesartan 30 mg; and takes amlodipine 1mg/kg and irbesartan 30mg/kg as the optimal dosage ratio; in the embodiment for making tablets, there were also compositions at the 1:30 ratio. This showed that the value 1:30 has been disclosed in the description; and

(2) For a claim to ratio relation, in the specific embodiment of the description could only be recorded the specific numerical value, and it was impossible to disclose an abstract ratio relation; the applicable dosage range clearly mentioned in the description of the patent in suit was amlodipine 2-10mg and irbesartan 50-300mg. If it was determined that the revealed optimal composition was merely 1mg:30mg, a specific dosage, not a ratio, the optimal composition did not at all fall within the said applicable range, which was obviously contrary to the common-sense knowledge. For a person skilled in the art, 1mg/kg and 30mg/kg indicated the ratio of two components, not a fixed dosage.

Issue 2: Whether amendment of the type was allowable in the invalidation proceedings

It was concluded in the invalidation decision that in the text of the issued patent, "1:10-30" was a technical solution, not two or more parallel technical solutions, and amending it into "1:30" in the phase of invalidation was contrary to the provision concerning ways of amendment in the invalidation proceedings.

It was noted in Judgment No.17 that the amendment was allowable for the following reasons:

(1) while the technical solution 1:10-30 in the initial claim was not a typical parallel technical solution, given the fact that the specific ratio value 1:30 was clearly recorded in the original description, and a recommended optimal dosage ratio, a person skilled in the art would conclude that the patent in suit included the 1:30 technical solution upon reading the original description, and in the claim of the patent in suit could only be found the variable 1:10-30. Such amendment rendered the claim more clear, and would not make the extent of protection fuzzy, so it was more fair to allow the amendment;

(2) the Implementing Regulations of the Patent Law and the Guidelines for Patent Examination limit the ways of amendment made to claims in the invalidation proceedings, on the one hand, to maintain the stability of the extent of protection of patents to ensure the indicative function thereof, and on the other, to prevent patentees from incorporating, in the patent claims, any technical solution that is not shown or at least not identified in the description before the filing date by way of post-amendment, so as to seize a prior filing date for a latter application. This circumstance was obviously absent in the present case. The value of 1:30 was the optimal ratio the patentee recommended in the original description, amendment into 1:30 in the claim neither went beyond the disclosure contained in the original description and claims, nor broaden the original extent of protection of the patent in suit, so not a circumstance to be avoided under the relevant law provisions on amendment to claims;

(3) if the amendment was not allowed as it was not a specified way of amendment according to the PRB, it would not be fair as the limitation on ways of amendment was turned into punishment, in the present case, on the patentee's improper drafting of the patent claim; and

(4) while the ways of amendments were limited to the three ways, such as deletion and combination of claims, and deletion of technical solution under the Guidelines for Patent Examination, other alternative ways of amendment are not absolutely excluded.

Case 2: Zeng Guansheng case

The case involved a patent application (00113917.7) relating to an invention of a mineral traditional Chinese medicament that could be applied or used externally and taken orally. In the application, a mineral Chinese medicament formed by addition of borax to an ancient powder medicant was claimed. In the original application, the components and

dosage of the mendicament were: mercury 8 "liang" (an old unit of weight in Chinese roughly equal to 1 gramme), alum 8 "liang", saltpeter 10 to 11 "liang", and borax 5 fen, (an old unit of weight in China roughly equal to 1/2 gramme or 1/10 qian). During the substantive examination, the applicant used "gramme" in replacement of "liang" based on the conversion rate "1 liang=30 grammes" according to the examiner's opinion, and the latter accepted the amendment, but rejected the application on some other grounds. During the reexamination procedure, the collegial panel maintained the rejection decision (namely in the Reexamination Decision No. 20574, the Reexamination Decision for short) on the ground that the amendment "1 liang = 30 grammes" was contrary to Article 33 of the Patent Law.

Both the courts of first and second instance maintained the Reexamination Decision made by the PRB. Dissatisfied with the second-instance judgment, Zeng Guansheng requested the Supreme People's Court to retry the case, and the Supreme People's Court ruled to have reversed the second-instance judgment Administrative Judgment No. Zhixingzi 54/2011, the Judgment No.54 for short).

The issue was whether the amendment made in the old unit of weight from "liang" into "gramme" based on "one liang = 30 grammes" has gone beyond the scope of disclosure contained in the initial application.

It was found so in the PRB's Reexamination Decision on the following grounds:

(1) in the description of the application in suit was not made clear whether the term of unit "liang" was used in the new or the old system of unit of weight, so it was impossible to solely determine that "liang" was used in the old system in the present application; and

(2) even if it was possible to determine that the "liang" of the old system was used, one "liang" in the old system was equal to 31.25 grammes, then 10-to-11-liang saltpeter was not equal to 300-to-330-gramme saltpeter. While the applicant pointed out, in appendix 1, that it was possible to cast out the mantissa, the appendix 1 did not make it clear that the way to do so was to cast out 1.25 grammes, namely, one "liang" was equal to 30 grammes.

A conclusion exactly opposite to the Reexamination Decision was made in Judgment No.54 on these grounds:

(1) while there were old and new systems for conversion of "liang" into "gramme", in the prescription of the traditional Chinese medicine, the old system of "one jin (a unit of weight in China) = 16 liang" as followed. The present patent application was derived by improvement of an ancient prescription of elixir of three medical herbs (**三仙丹**). hence while in the description was not mentioned by what system "liang" was converted into "gramme", a person skilled in the art was sure that "liang" was converted into "gramme" by the old system according to the technical background of the patent in suit, content of invention and the general knowledge in the art, and the new "one-jing-equal-to-10-gram" system should not be used;

(2) according to the evidence[2] submitted when retrial was requested, under the old system for converting "qian" (unit of weight in China) into "gramme", one "qian was equal to 3 grammes. Since "one liang = 10 qian", one "liang" should obviously be 30g under the old system, which was also followed in the other evidence. Therefore, "casting out the mantissa in the conversion" mentioned in appendix 1 should be construed by a person skilled in the art as meaning that the mantissa was "1.25" in "31.25 grammes", namely on the basis of "one liang = 30 grammes";

(3) choosing various methods of casting out the mantissa under the old system was what a person skilled in the art could directly and unambiguously determined, without introducing any new technical content and causing prejudice to the public interests, nor "was it possible to so substantially change the technical solution of the present invention" as the PRB was concerned "as to render an unworkable technical solution into a workable one"; and

(4) during the substantive examination of the patent application in suit, the State Intellectual Property Office (SIPO) first invited Zeng Guansheng to make amendment in relation to the unit of weight "liang", and then expressly accepted his use of conversion "one liang = 30 grammes". Besides, in the invalidation decision and first and second instance judgments was neither sufficiently considered the special characteristics of the art to which the patent application pertinent and the knowledge a person skilled in the art should have, nor the reason for which Zeng Guansheng amended the application and the fact that the way of amendment was accepted by the SIPO; under the circumstance of whether there was nothing undue mentioned in the Office Action, it was erroneous to have determined that Zeng Guansheng's amendment to the application in suit went beyond the scope of disclosure contained in the original description and claims, so was it so in the ascertainment of the fact and in the application of law.

II. Provisions pertaining to amendment to patent applications and the legislative aim thereof

It is provided in Article 33 of the Patent Law that an applicant may amend his or its application for a patent, but the amendment to the application for a patent for invention or utility model may not go beyond the scope of the disclosure contained in the initial description and claims, and the amendment to the application for a patent for design may not go beyond the scope of the disclosure as shown in the initial drawings or photographs. The provision is further interpreted in Chapter 8 of Part II of the Guidelines for Patent Examination that the scope of the disclosure contained in the initial description and claims includes the contents described in the initial description and claims, and the contents determined directly and unambiguously according to the contents described in the initial description and claims, and the drawings of the description.

Article 33 of the Patent Law has two layers of meanings: 1) an applicant is allowed to amend his application to rectify any error that occurs in a drafted application; and 2) there must be limitations imposed on amendment an applicant makes to an application, and not all errors are rectifiable.

The reason for allowing an applicant to amend his application in the course of patent prosecution is that due to the limitation in terms of language and expression of an applicant in drafting his application, disallowing him to amend his application would make it impossible for his technical contribution he has made to the society to be properly protected; now, allowing him to make corrections by way of amendment to an application would help the public to obtain correct technical information, and correctly construe the patent right. However, when an applicant amends his application, amending an application without changing the date of filing would make it impossible to ensure that the patent he is granted relates to an invention he has made on that day if his amendment is not limited to the scope of information of the disclosure of the application as filed, which is essentially contrary to the first-to-file doctrine. Meanwhile, it may become a disguised encouragement for some applicants not to disclose important technical content in the early stage of application, but to gradually improve his application by way of amendment if necessary in the course of patent prosecution, which would make the patent application and the claims made therein indefinite, the public less sure of and less confident in the patent, and the public interest be seized by someone unlawfully.

Anyway, the Patent Law allows applicants to rectify errors in applications, and, as well, imposes limitation on the scope of rectification they make to satisfy the system of first-to-file requirement, and, more importantly, to balance the interests of the rightholder and those of the public.

III. Thoughts on patent examination

The preceding two cases just involve two levels of issues concerning amendment to applications. Case 1 shows what clear disclosure in application is; and case 2 involves how "directly, unambiguously determine" should be understood. With the conclusion made by the Supreme People's Court in its decisions, it is no longer meaningful to argue which is substantially right or wrong in the two cases *per se*. What is essential is to learn lessons and draw experience from them and to improve our adjudication. For this writer, light has been thrown on issues behind the cases that require our attention.

1. Avoiding mechanical application of law provisions

Patent examination requires thorough understanding of natural science and relevant law provisions. The key in patent examination is to make certain about the core information of an invention-creation, and understand it technologically, rather than give attention merely to the literal meaning; specific law provisions are applied with the legislative spirit borne in mind, rather than focusing too much on particular words in them.

One of the issues involved in case 1 was whether amendment of the ratio of amlodipine and irbesartan at 1:10-50 into 1:30 was allowable. To address the issue, following questions should be answered besides considering whether the ratio 1:30 was clearly mentioned in the application in suit.

(1) As the amendment involved in the case was one of the range of numerical value, what provisions have been set forth in the Guidelines for Patent Examination concerning amendment to range of numerical value? And why are they set forth this way?

(2) What is the substance of the patented invention in suit? Why did the applicant define the ratio of the two components? Why was the ratio amended during the examination of the patent application?

(3) What was disclosed in the description? Was the em-

bodiment of composition of 1mg/kg amlodipine and 30mg/kg irbesartan used in the test of activity of pharmacology of rat in the description a clear statement of the ratio"1:30"?

(4) If the embodiment of the composition of 1mg/kg amlodipine and 30 mg/kg irbesartan could only serve as one of the specific dosage, not a clear presentation of the ratio"1:30", what data did the inventor need to give and how should he draft the application when he wanted to protect the technical solution of the abstract ratio relation "1:30"?

(5) The value of 1:30 was derived from the amendment to the range of numerical value 1:10-50, how was the technical solution represented by the end point of 1:10 and 1:50 recorded in the original application?

If the five questions are considered comprehensively, the examination procedure would be flawless whatever conclusion is drawn from it.

2. Avoiding issuance of Office Actions "blocking at both ends"

Patent examination is to find out whether an invention-creation has made contribution to the society and whether there is a technical solution in the patent application that is worth giving its monopoly for a period of time, and eventually strike a balance between the interest of the rightholder and that of the general public. For this purpose, unless there is nothing worth protection in a patent application or there are substantial flaws, so that it is impossible to accord it protection, comprehensive account should be taken as much as possible of the law provisions to apply and the possible amendments to be made by the applicant, to help identify the true innovative point and draw the border line around the invention-creation. Any Office Actions "blocking at both ends" should be avoided as much as possible to prevent the circumstance from arising where the rightholder would find no way out.

The issue of case 2 is whether the applicant's amendment of "liang", a unit of weight in the Chinese system used in the ancient prescription of the traditional Chinese medicine, by converting it into "gramme" on the basis of "one liang=30 grammes" was allowable. As the history of the patent prosecution showed, the applicant made the amendment as the examiner so pointed out in the second Office Action that "liang" was not a generally used international unit of weight, and required him to make the amendment to it. During the reexamination of the case, the collegial panel raised these questions: was it necessary to point out this matter in the Office Action? And would the application be rejected if the applicant did not make the amendment?

Of course, it should be said that this Office Action fully complies with the provision of the Guidelines for Patent Examination. Any experienced applicant or patent attorney would possibly not choose to amend the application to avoid any unnecessary problem, and would only clarify the matter in his observations directed to the Office Action. But, there are many inexperienced applicants or patent attorneys in practice. How to make Office Actions legal and due or reasonable, and, meanwhile, take care of particular circumstances of various cases is a great difficulty before us. For the writer, the key to addressing the matter is to comprehensively consider the consistence between the entire case and the Office Action, and avoid mechanical application of any law provisions to all cases, with the examination standards kept consistent.

3. Taking more consideration of legislative aim

Whether an amendment is allowable to a patent application depends, on the one hand, on whether the interest of a rightholder is kept in balance with that of the public, and, on the other, on whether the amendment is against the first-to-file system. Therefore, during the patent examination, when a choice is hard to make in case of an applicant's amendment, more consideration should be taken of the legislative aim. That is, if his amendment is allowable, will the applicant obtain any extra benefits or would prejudice be caused to the public interests? If his amendment is not allowed, will the interests of the rightholder and the public be kept in balance?

In case 1, the primary reason for the Supreme People's Court to have decided to reverse the invalidation decision is that the applicant had clearly identified the value 1:30 as the optimal dosage ratio in the original application. With the amendment in relation to the ratio not going beyond the scope of disclosure contained in the original application, if the applicant's failure to put the optimal technical solution in the dependent claim resulted in loss of his right for not satisfying the requirement on ways of amendment in the invalidation proceedings, it would render his contribution made to the society obviously not equivalent to the benefit he is entitled to, and knock the interest of the rightholder and that of the public out of balance. While there are still something worth probing into in the Supreme People's Court's decision, we can learn something useful in this aspect, that is, when it is hard to make a choice, taking more consideration of the legislative aim will help avoid making legal, but unfair conclu-

sion.

IV. Impact on patent system

In case 1, the Supreme People's Court pointed out with regard to the methods of amendment: "moreover, it is provided in the Guidelines for Patent Examination that, with the principles of amendment satisfied, there are only three abovementioned methods of amendment, without absolutely excluding other methods of amendment." This point of view leads to antoher issue, namely, the issue of reasonability of the provisions governing the methods of amendment to the patent application and the practice of examination thereof in the invalidation proceedings.

Regarding amendment to patent applications in the invalidation proceedings, Rule 69 of the Implementing Regulations of the Patent Law provides: "in the course of the examination of the request for invalidation, the patentee for the patent for invention or utility model concerned may amend its or his claims, but may not broaden the extent of patent protection. The patentee for the patent for invention or utility model concerned may not amend its or his description or drawings. The patentee for the patent for design concerned may not amend its or his drawings, photographs or the brief explanation of the design." Section 4.6, Chapter 3 of Part IV of the Guidelines for Patent Examination has further set forth detailed provisions in relation to the principle, methods and timing of amendment. Regarding the methods of amendment, it is provided that with the principles of amendment satisfied, the specific methods of amendment are generally limited to deletion and combination of claims, and deletion of technical solution.

The provision is set forth in the Guidelines for Patent Examination out of two considerations. One is the balance between the interests of a rightholder and those of the public at large. In the invalidation proceedings, a patentee is allowed to amend his patent documents to rectify errors existing in the patent prosecution. But absence of limitation imposed on amendment to an issued patent, especially on amendment to the claims of the patent would make things uncertain for the public, and render the Patent Office's patent grant publication unreliable. For this reason, not all errors are rectifiable. Two is the necessity for the sake of efficient examination in the patent right affirmation procedure. Very often, behind an invalidation case is an infringement dispute; if the latter is not resolved within a short period of time, the economic interests of both parties would be greatly affected, and the validity of the patent right at issue is the basis on which infringement is found. If the dispute over a patent right remains unresolved in a prolonged period, it would greatly affect the resolution of the infringement dispute. One of the main reasons for prolonged examination of an invalidation case is the patentee's amendments to his patent, with invalidation grounds and evidence incessantly increased. In this situation, the Guidelines for Patent Examination seek to duly limit, the ways a patentee is allowed to amend his patent to regulate the rights and obligations of both parties and those of the rightholder and the general public, and to help standardize the examination procedure.

As the expressions of the Guidelines for Patent Examination often show, the word "generally" means very few exceptions. For this matter, in their examination practice, most collegial panels would understand "the amendments are" generally limited to "in the Guidelines for Patent Examination" as meaning "limit only to", and refuse to accept all ways of amendment other than the specified three. It is true that this understanding helps address many issues in the examination practice, such as consistence in examination, but it also causes many doubts. For example, on the one hand, a panel would not allow a patentee to amend an obvious error in the claim; on the other, take it as such in the invalidation decision, and come up with a corrected reading of it, and would not invalidate the patent because of the error. This practice is suspected as "allowing one to steal a horse, but disallowing another to look over the hedge".

Additionally, some scholars have challenged the understanding from the angle of administrative licensing law. According the principle of the administrative licensing law, regulations of an administrative authority should only set forth detailed provisions of the relevant administrative law provisions, and should not add any new provisions. The phrase "generally limited to" is used in the Guidelines for Patent Examination to recommend and list the allowable methods of amendment for the purpose of giving a detailed explanation of Rule 69 of the Implementing Regulations of the Patent Law. But understanding the term as meaning "limited only to" greatly narrows down the scope of the provision of Rule 69, and is essentially contrary to the administrative licensing law as the basis to evaluate the relationship between the Patent Law and the Implementing Regulations of the Patent Law and Guidelines for Patent Examination is open to question. This, however, reminds us to consider another issue: is the understanding of the ways of amendment reasonable.

In case 1, the Supreme People's Court has only made it clear that the ways of amendment to patent in the invalidation proceedings should not limited only to the three methods, namely deletion and combination of claims, and deletion of technical solution, but does no give its opinion on under what circumstances an amendment other than those of the three methods of amendment should be acceptable or unacceptable. The taking into effect of the Supreme People's Court decision is likely to cause some conceptual confusion in the industry within a period of time, and make the PRB's enforcement more difficult. How to address the relation between legality and reasonability, with ensured consistent standards of examination, is an urge task lying before us.

For this writer, addressing the issue requires consideration of two aspects. One is to amplify the provisions concerning amendment to patent in the invalidation proceedings within the framework of the current laws and regulations. For example, scrutinising the possible ways of amendment by patentees in practice and studying the issue likely to be caused by the various ways of amendment, so as to come up with requirements complying with the laws and regulations and, as well, ways to address issue of reasonability or fairness in particular cases. The other is to make foresighted research in respect of system design. Factors affecting the patent quality are many, and attention given and importance attached by applicants and patentees to patent quality is also an indispensible factor to ensure the quality of patents, besides importance attached to the quality in the phase of examination. If patentees are made more active in paying attention to the quality of patent documents as a result of the designed system, it would reduce the incidence of contradictions as caused from amendment in the invalidation proceedings. For example, after a patent is issued, the patentee is allowed to rectify errors within a period of time, a lenient attitude is adopt towards amendment in the period. If a patentee is inactive in exercising his right, he would miss the chance to rectify errors to amend his patent documents, then after the period expires, severe limitation is imposed on the patentee's amendment to his patent in the invalidation proceedings.

V. Conclusion

Anyway, nothing is absolutely right or wrong in patent examination, and outcome of examination is often embodied in the values within the framework of the current law. China is not a case law country, and the Supreme People's Court's decisions or judgments are not binding on the SIPO's examination, but we should study and draw on the judicial spirit as embodied therein. By drawing on views or opinions of all sides, examiners will improve their concept of examination, make the examination standards more consistent, and increased their impact on the whole society. ■

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[1] The Article 33 provides that the amendment to the application for a patent for invention or utility model may not go beyond the scope of the disclosure contained in the initial description and claims.

[2] Namely, the Report, for Instruction, of National Standards and Measurements Bureau's Report on Unit of Measurement in Prescriptions of Traditional Chinese Medicine as Reissued by the State Council.