Assessing Inventiveness in Patent Invalidation Procedure

Comments on Wellman Corp. v. PRB, Shuanghe Corp., Supreme People's Court's Judgment No. Xingtizi 8/2011.

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Under the Chinese Patent Law (CPL), "inventiveness means that, as compared with the prior art, the invention has prominent substantive features and represents notable progress, or the utility model has substantive features and represents progress",[1] and the description serves the function to disclose the invention or utility model (both referred to as "inventions") as claimed "in a sufficiently clear and complete manner" so that a person skilled in the art can carry out the invention without undue burden.[2] But the description is not required to disclose all the relevant prior art. It follows that there is no direct legal relationship between assessment of the inventiveness of a claimed invention and the disclosure of the description. In a recent administrative case (the Supreme People's Court's Judgment No.Xingtizi 8/2011), however, the Supreme People's Court (SPC) held that "the technical solution or effect which is not disclosed in the description should generally not be relied upon to decide whether the application meets the patentability requirements …." In effect, the court ruled that inventiveness should be assessed in the light of the technical solution or effect as disclosed in the description. Is this a new rule of law? It is worthwhile to elaborate this new development. The case could be quite influential, as the SPC has selected it to provide persuasive guidance for lower courts.

I. Legal Context

Article 22 of the CPL is a general provision for inventiveness, and difficult to apply. Under Chapter 4 of Part 2 of the Guidelines for Patent Examination (the GPE) as of 2010, to assess inventiveness, the following three steps should be followed: first, determine the closest prior art; second, determine the distinguishing features of the invention, and the technical problem actually solved by the invention; and third, determine whether or not the claimed invention is obvious to a person skilled in the art. It should be noted that it is the second step where the disclosure of the description can play a significant role in assessing inventiveness. The GPE has made it clear that because the closest prior art identified by the examiner is possibly different from that mentioned in the description, the technical problem actually solved by the invention, which should be re-determined in view of the closest prior art, may not be the same as that mentioned in the description. In principle, any technical effect of the claimed invention may be relied upon as the basis to re-determine the technical problem "as long as the technical effect could be recognised by a person skilled in the art from the contents set forth in the description".[3]

II. Proceedings

The patent in suit (application No. 97108942.6), called "anti-β-lactamase antibiotic composition", granted on 6 December 2000, was transferred from the Guangzhou Wellman Corporation to the Xiangbei Wellman Corporation ("Wellman") on 22 June 2007. The patent has only one claim: "1. A anti-β-lactamase antibiotic composition, comprising sulbactam, and piperacillion or cefotaxime, in the ratio of 0.5~2:0.5~2."

In December 2002, the Shuanghe Pharmaceutical Corporation (Shuanghe) filed a request with the Patent Reexamination Board (PRB) to declare the patent invalid on the ground that claim 1 was not novel or inventive. In particular, Shuanghe submitted an English paper as evidence (the Document). In the introduction of this paper was pointed out that the main reason that bacteria are resistant to β-lactam antibi-

otics is its ability to produce β-lactamase. It was suggested that sulbactam, when administered in combination with piperacillion at the ratio of 0.5:2 or with cefotaxime at 1:2, can strengthen antibacterial effects, broaden antibacterial spectrum, and thus reduce antibiotic resistance. It was noted that the Agar diffusion test showed that all subject microorganisms were sensitive to the composite preparation comprising 15μg sulbactam and 30μg antibiotic".

Relying on the description of the patent, the PRB found that: 1) the technical solution of claim 1 was to solve the following technical problem: antibiotic resistance to piperacillion and cefotaxime flowing from the production of antiβ-lactamase; (2) claim 1 provided the solution: a composite preparation comprising sulbactam, and piperacillion or cefotaxime, mixed at the ratio of 0.5~2: 0.5~2; (3) this solution would improve antibacterial activity, broaden antibacterial spectrum and reduce antibiotic resistance.

Based on the finding, the PRB held that a person skilled in the art, drawing on the technical solution disclosed in the prior art and, in particular, the teaching given therein (all subject microorganisms are sensitive to the composite preparation made of 15μg sulbactam and 30μg antibiotic), would have inferred a solution of a composite preparation comprising sulbactam and piperacillion or cefotaxime without undue burden. That is, the skilled person would have arrived at the technical solution of claim 1 and achieved the same technical effect. Accordingly, the PRB made Decision No. 8113, declaring the patent invalid for lack of inventiveness. In addition, the PRB noted that: "the patentee submitted that the claimed invention possessed other technical effects, such as side effect reduction, equivalent activity and high bio-effect. Because all the effects are not disclosed in the description, they are inadmissible to prove that claim 1 is inventive."

Dissatisfied with the decision, Wellman brought an administrative suit before the Beijing No. 1 Intermediate People's Court, which found that, compared with the technical solution disclosed in the Document, claim 1 distinguished itself because said composite preparation was made by mixing sulbactam and piperacillion or cefotaxime at 0.5~2: 0.5~2". The court underscored that the Document showed that combined administration of the medicaments had good therapeutic effect. Relying on this disclosure as a springboard, a person skilled in the art would have arrived at the technical solution of claim 1 by making composite preparation comprising sulbactam and piperacillion or cefotaxime through ordinary skills and achieved said technical effect. Consequently, the court held that the patent was not inventive.

Dissatisfied with this judgment, Wellman appealed to the Beijing Higher People's Court. This time, the court found that while the Document disclosed that sulbactam in combination with piperacillion or with cefotaxime could make composite liquid for injection, it did not show specifically the technical solution to make them into a composite preparation. Furthermore, the court accepted this argument submitted by Wellman as convincing: "combined administration of multiple medicaments" and "composite preparation comprising multiple medicaments" were two distinct concepts and the solution to bridge their fundamental differences was not necessarily obvious to a person skilled in the art. The court also ruled that the PRB's decision under appeal failed to give any evidence to support the following decision: "a person skilled in the art would have inferred a solution of a composite preparation comprising sulbactam and piperacillion or cefotaxime without undue burden" and that the decision was not well founded. In short, the court reversed the judgment below.

Dissatisfied with this judgment, Shuanghe petitioned the SPC for *certiorari*. In response, Wellman submitted that the claimed invention was a composite preparation suitable for human use, meeting the conditions required by the State Drug Administration to be safe, effective and stable. To achieve these effects, the invention had gone through relevant experiments and tests. While they were not disclosed in the description, the validity of the patent was not prejudiced because the description met the requirements set forth in the GPE. Furthermore, while the Document disclosed that antibiotics, sulbactam and bacterial-free water could be mixed and administered together to achieve better therapeutic effects, it was not disclosed that they could form a safe, stable composite preparation with synergetic effect. In sum, the patent was inventive.

Having heard the case, the SPC ruled that a pharmaceutical invention, satisfying all the statutory requirements for the grant of a patent, should be patentable irrespective of whether it met other legal provisions regulating its development and production. The SPC held that "the technical contents disclosed in the description at the applicant's filing of the application should serve as the basis for the Patent Administrative Authority under the State Council to examine the application … . The technical solution or effect which is not

disclosed in the description should generally not be relied upon in deciding whether or not the application meets the patentability requirements … . Any holding otherwise would conflict with the first-to-file principle, and depart from the essence of patent right, a legal monopoly which may only be granted in exchange of sufficient disclosure". In the SPC's opinion, because the experiments and tests to determine the safety, effectiveness and stability of the composite preparation was not disclosed in the description, they could not represent the innovative improvement and contribution of the claimed invention to the prior art, and must not be relied upon in assessing the inventiveness of the invention. In line with the other findings, the court decided to have reversed the judgment of second instance, and affirmed the judgment of first instance.

III. Analysis and comments

The above SPC judgment gives an illusion that it has made a new rule of law. Note there is no specific legal provision for any direct legal relationship between inventiveness and the description. Instead of citing any specific rules, the judgment proceeded in line with the general principles and even theories, giving an impression that there has been made a new rule. This illusion, however, evaporates when the judgment is reviewed through the normal steps for the assessment of inventiveness, in particular, the sub-steps of "determining the distinguishing features of the invention" and "determining the technical problem actually solved by the invention".

1. Assessing Inventiveness and reformulating technical problem

Where a patent is challenged for lack of inventiveness, the following issue usually arises: the technical problem actually solved by the invention has to be reformulated. The requester, when carrying the burden to prove that a patent is devoid of inventiveness, would come up with new references, which are likely to be different from the prior art as mentioned in the description and was relied on by the examiner, but in all likelihood are closer to the claimed technical solution. One of the references should be established as "the closest prior art". As a result, the technical problem which was mentioned in the description and determined by the examiner is no longer the technical problem "actually" (or, to be precise, "objectively") solved by the invention. Therefore, it is necessary to reformulate the technical problem first, and then proceed with the assessment made as to whether the distinguishing features of the claimed invention are obvious or not.

Nonetheless, there is no provision in the GPE on whether it is allowable to reformulate the technical problem "actually" solved by the invention in invalidation proceedings. In Decision No. 8113, the PRB made it clear how to assess inventiveness in the invalidation proceedings: "in determining whether an invention has prominent substantive feature relative to the prior art, one should first determine a technical solution in the prior art which is the most closely related to the claimed invention, then determine the distinguishing features of the claimed invention as compared with the closest prior art, and lastly determine whether the distinguishing technical features would render the claimed technical solution obvious or not to a person skilled in the art." In comparison to the relevant GPE provision for assessing inventiveness in examination, it seems that this application of law omitted the sub-step of determining the technical problem actually solved by the invention. Neither the Beijing No. 1 Intermediate People's Court, nor the Beijing Higher People's Court, nor the SPC, addressed this matter.

In fact, Wellman had requested the tribunals to reformulate the technical problem. In view of the Document submitted by Shuanghe, Wellman argued that a composite preparation comprising multiple medicaments was different from the combined administration of multiple medicaments because the former was required to be safe, stable and effective as to be suitable for human use in conformity with the regulations made by the State Drug Administration. In effect, Wellman submitted that the following statement in the description should not be binding: "the present invention is intended to solve the problem of antibiotic resistance to piperacillion and cefotaxime". The tribunals should have decided whether, in the light of the knowledge and capability of a person skilled in the art on the filing date or priority date, the technical problem actually solved by the invention should be reformulated on the basis of the closest prior art newly established as follows: making a composite preparation comprising piperacillion or cefotaxime suitable for human use and counteracting antibiotic resistance. There is no doubt that a person skilled in the art would have formulated this technical problem because the Document disclosed the technical solution of administering sulbactam in combination with piperacillion at 0.5:2 or with cefotaxime at 1:2, and in the description of the patent was mentioned that "to date, there

is no report on clinical use of a composite preparation comprising sulbactam and piperacillion or cefotaxime." But it is not clear from the description whether the claimed invention has "actually" solved this technical problem since it only disclosed tests which could prove improved anti-bacterial effect of the claimed invention.[4]

With regard to reformulating the technical problem, neither the PRB's Decision, nor the SPC's judgment dealt with it in explicit terms, but both underlined that a technical effect not presented in the description should not be relied upon to assess inventiveness. In so doing, the PRB and the SPC were in effect examining the above Wellman's submission for the technical problem in the light of the following GPE provision: "as a principle, any technical effect of an invention may be used as the basis to re-determine the technical problem so long as the technical effect could be recognised by a person skilled in the art from the contents on the description".[5] It is thus shown that in practice, a patentee may, in the invalidation proceedings, request to reformulate the technical problem actually solved by the invention.

Nevertheless, the standard that "the technical effect could be recognised by a person skilled in the art from the contents of the description" is very much likely to cause controversy. In this case, while the PRB required that the technical effect claimed by the patentee be "recorded" in the description, the SPC required that such technical effect be "disclosed" in the description. It is worth noting that in practice, "recorded" and "disclosed" are two different legal standards, subject to long-standing contraversy.[6] Moreover, as the SPC linked the disclosure of the description under this circumstance with the "first-to-file principle", it is quite likely that reformulating the technical problem would be decided upon in the light of Article 33 of the CPL, which prohibits extension of subject matter by way of amendment made to the patent application. This would open to a whole set of legal issues.

2. Assessing Inventiveness and reformulating distinguishing features

Similar to reformulating the technical problem, the distinguishing features of the invention should be reformulated in view of a reference of the prior art newly submitted by the invalidation requester in order to assess the inventiveness of the challenged invention. A simple comparison made between the claim and the reference will not do. Thus, the patentee and the requester often have dispute over the construction of the claims. The patentee would advocate strongly for a narrow interpretation so as to maximise the possibility that the claims would be maintained as valid.[7] But any claim must be construed on the basis of the disclosure of the description.

In this case, Wellman submitted that "composite preparation" as claimed was a safe, effective and stable medicament suitable for human use. In effect, Wellman was re-interpreting the disputed claim. But the SPC took an ambivalent position on this matter. On the one hand, the SPC dwelled on the difference and connection between "a composite preparation of multiple medicaments" and "the combined administration of multiple medicaments", recognising that the term "composite preparation" was a special one understood by a person skilled in the art as meaning a safe, effective and stable medicament suitable for human use. On the other, the SPC held that a pharmaceutical invention, satisfying all the statutory patentability requirements, should be patentable, irrespective of whether it meets the other legal provisions regulating its development and production. In so doing, the SPC averted the important legal issue.

In fact, Wellman's interpretation of "composite preparation" should be acceptable. If the claim is so interpreted, however, the claim could not be supported by the description, or was not so sufficiently disclosed in the description as to enable a person skilled in the art to carry out the invention. The description did not give any test data to show whether the composite preparation of claim 1 was safe, effective and stable for human use. But Shuanghe challenged claim 1 for lack of inventiveness. A legal issue thus arises whether the courts may declare the claim invalid for lack of support from the description or for "insufficient disclosure" even though these grounds were never raised by the requester Shuanghe?

The SPC implicitly gave a positive answer. The SPC noted that the description did not give any test data and research results to prove that the claimed composite preparation was safe, effective and stable for human use. The court reasoned that they could not reflect the innovative improvement and contribution of claimed invention to the prior art, and, thus, "shall not be relied upon in assessing whether the claimed invention was inventive or not." In effect, the court held that the claimed solution of composite preparation was not sufficiently disclosed. If so, that inventiveness should be assessed in the light of the technical solution or effect disclosed in the description should not be regarded as a new rule. It is nothing but a conclusive legal opinion deduced

from multiple rules through several steps of reasoning. This shows that the SPC complicated the problem unnecessarily.

The SPC should have answered the following question in a positive manner: in the patent invalidation proceedings (including first instance, second instance, and hearing under *certiorari*), if the court has reached a new interpretation of the claim which would cause the disputed claim to be declared invalid on a ground not raised by the party, may the court hear arguments from the parties and declare the claim invalid on that ground? This is not a simple issue. On the one hand, if the court refuses to do so, the party would have to file another invalidation request or go back to the PRB for another hearing upon the remitting of the case; on the other, if the court can decide the case in this manner, it is quite probable for the case not to be reviewed, with the court acting as a trial tribunal. This practice would prejudice the procedural rights of the parities. Therefore, there is no simple answer. In principle, it should be decided on the merits of individual cases. However, where the available evidence is sufficient to show that the disputed claim is invalid on the new ground, the court should decide accordingly for the sake of judicial economy, provided that the procedural rights of the parties would not be materially prejudiced.

Concluding remarks

Both of the above two lines of reasoning can lend normative meaning to the SPC judgment, but they touch upon different issues of law. Because the SPC was reasoning through general patent law principles without citing any specific legal provision, it is very difficult to sort out which line of reasoning the court intended the lower courts to follow in the future. The principles should be relied on only when specific rules fail to address a given legal issue, otherwise, the application of principles may disrupt the legal order and bring about undesirable, but harmful, legal uncertainty. ■

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[1] See Article 22, paragraph two, of the CPL.

[2] See Article 26, paragraph three of the CPL.

[3] Part 2 of Chapter 4 of the GPE as of 2010, P. 172.

[4] Description of the patent in suit, P. 5.

[5] See supra note 3.

[6] See Huaiwen He, Allowbility of Amendment During Patent Grant Procedure: Comments on Zheng Yali v. Epson Corp., et al., Supreme People's Court（2010 Zhi-Xing-Zi Case No.53）, China Patents & Trademarks 2012, issue 3, P. 39.

[7] In the present case, Wellman submitted that claim 1 was a close-end one, and it was obvious for a person skilled in the art to understand the term "composite preparation" as meaning "(frozen dry) powder injection agent". The SPC, however, rejected this argument.