Latest Developments in Adjudication of IP Cases by Beijing Higher People's Court in 2015

(Abridged Part on Patent)

The IP Tribunal of the Beijing Higher People's Court

In the year of 2015, the Beijing Higher People's Court accepted 2,950 IP cases (inclusive of old files) of all types, representing a 17.34% year-over-year increase, of which there are 6 first-instance cases, 2,904 second-instance cases and 40 appeals. Of all the accepted cases, administrative cases involving grant and validity of IP rights amounted to 2,239, accounting for 75.90% of all the cases accepted; and IP-related civil cases amounted to 665, taking up 24.10% of all the cases accepted. Of all the 2,239 administrative cases involving grant and validity of IP rights accepted in 2015, administrative cases involving patent grant and validity amounted to 178, making up 7.95%, and administrative cases involving trademark grant and validity amounted to 2,061, making up 92.05%.

In the year of 2015, the Beijing Higher People's Court closed 2,422 IP cases of all types, representing a 9.49% year-over-year increase, of which there is 1 first-instance case, 2,389 second-instance cases and 32 appeals. Of all the closed cases, administrative cases involving grant and validity of IP rights amounted to 2,312, accounting for 95.46% of all the cases closed; and IP-related civil cases amounted to 110, taking up 4.54% of all the cases closed. Of all the 2,312 administrative cases involving grant and validity of IP rights closed in 2015, administrative cases involving patent grant and validity amounted to 235, making up 10.16% , and administrative cases involving trademark grant and validity amounted to 2,077, making up 89.84%.

This article will present an overview of the latest developments and updates of the Beijing Higher People's Court in adjudication of IP cases in 2015.

I. Administrative cases involving patent grant and validity

Determination of whether a claim containing the word "comprise or comprising" is an open-ended claim

As to patent claims in the mechanical field, they shall not be considered as open-ended just because of the inclusion of the word "comprise or comprising" therein or allowed to be added with other components at will. Whether such a claim is open-ended should be determined in the context of description, claims and drawings.

In *Xu Yan v. Patent Reexamination Board (PRB) & Zhang Ying* [1], namely an administrative dispute over invalidation of an invention patent, the patent at issue (No.200710111081.2) is an invention entitled "hollow slab for installing permanent assembling units and implementing method thereof" and owned by Xu Yan. Claim 1 of the present patent at the time of issuance reads "1. A hollow slab for installing permanent assembling units, comprising an upper-layered rebar (1), a lower-layered rebar (2), concrete (3) and assembling units (4), the assembling units (4) being located between the upper-layered rebar (1) and the lower-layered rebar (2) and permanently embedded in the concrete (3), characterized in that the assembling units (4) are oriented in a direction identical with the shearing force transmitting direction in the plate where they are located, and in the lengthwise direction of rob-shaped fillers in the assembling unit." Zhang Ying submitted a request with the PRB for declaring the present patent invalid. The PRB held in the Decision appealed that claim 1 of the patent at issue is an open-ended claim as being drafted in a format of "a

hollow slab……, comprising……", so it cannot be deemed that the hollow slab merely has those components as defined, no other components such as hidden beams. Claim 1 of the patent at issue comprises the technical solution that the hollow slab is a one-way slab, and those skilled in the art all know that in the one-way slab, the direction in which the bending moment is greater is identical with the shearing force transmitting direction. However, D1 discloses the technical solution that in the one-way slab, the direction in which the combination unit is arranged is identical with the shearing force transmitting direction, that is to say, D1 has disclosed a technical solution that is substantially the same as that of claim 1. In addition, both D1 and the present patent pertain to a hollow slab used for a floor, solve the technical problem of improving the anti-shearing performance of the hollow slab, and attain the same technical effect. As a result, claim 1 of the patent at issue lacks novelty over D1. The first-instance court agreed with the above opinion.

The second-instance court ruled that the key to determine the scope of protection of claim 1 of the patent at issue is to clarify the meaning of the word "comprising", in other words, whether claim 1 is an open-ended claim or a closed-ended claim. That word shall be interpreted in conjunction with the contents of claim 1, the description and drawings. Claim 1 of the present patent claims a hollow slab for installing permanent assembling units, and it is clearly recited in the description of the present patent that "the slab does not need stirrups therein, which greatly simplifies the construction process", from which it can be told that claim 1 of the present patent has no hidden beams. The hidden beam and the hidden beam rebar are involved in a one-to-one relationship. In the absence of the hidden beam, claim 1 does not have the hidden beam rebar. The court of original jurisdiction and the PRB erred in finding claim 1 as open-ended and having the hidden beam just because of the word "comprising" contained therein, which is apparently contrary to the description of the present patent.

Holistic principle in the assessment of inventive step

The holistic principle shall be abided by when assessing the inventive step of a patent. By the holistic principle in the assessment of inventive step, it means that the technical solutions, the technical problem intended to be solved and the technical effect to be attained shall be considered as a whole in assessing whether the invention or utility model possesses inventive step or not. According to that principle, if one of the technical problem, technical solution and technical effect of an invention is non-obvious, it may render the entire technical solution non-obvious. If the technical problem to be solved can be readily conceived by a person skilled in the art, the technical means used for solving the technical problem may easily occur to a person skilled in the art and no unexpected technical effect is produced, then the technical solution as a whole is obvious and lacks inventive step.

In *Shangdong Lvjian Energy-saving Technology Co., Ltd. (Lvjian Co.) v. PRB & Shijiazhuang Jingda Construction System Co., Ltd. (Jingda Co.)* [2], namely an administrative dispute over invalidation of a utility model, the patent at issue (No.201120269887.6) is a utility model entitled "steel wire net rack thermal-insulating board cast-in-situ reinforced concrete composite wall body structure" and owned by Lvjian Co. Claim 1 was amended as follows: "1. A steel wire net rack thermal-insulating board cast-in-situ reinforced concrete composite wall body structure, characterized in that it mainly consists of a thermal-insulating board, and an internal concrete layer and an external concrete layer at both sides of the thermal-insulating board, interface mortar layers are disposed between the thermal-insulating board and the internal concrete layer, as well as the external concrete layer, the external side of the thermal-insulating board is covered by the interface mortar layer, a groove is disposed in one or both sides of the thermal-insulating board, the external side of the thermal-insulating board is provided with concrete or mortar cushion blocks, the steel wire net rack is implanted into the thermal-insulating board, the internal concrete layer and the external concrete layer and is connected with a connector, the connector is a structural rebar with ends in the shape of a ram's horn, 丁 or L; the connector is welded or anchored to the steel wire net rack; and the thermal-insulating board is selected from the group consisting of an expanded polystyrene board, an extruded polystyrene board, a phenolic foam board or an inorganic thermal-insulating board". Jingda Co. submitted a request with the PRB for declaring the present patent invalid, together with Attachment 1 which discloses a thermal-insulating layer built in an exterior concrete wall construction and the following contents: the thermal-insulating layer built in an exterior concrete wall construction is a thermal-insulating net rack board made by welding a polystyrene board 8 sandwiched between two steel meshes 7 to a 3D obliquely inserted rebar 11 (also known as abdominal wire), there is a

space between the polystyrene board 8 and the two steel meshes 7, the rebar 11 extends through the two ends of the polystyrene board 8 to be respectively welded to the steel meshes 7; the thermal-insulating net rack board is casted with concrete at internal and external sides simultaneously, the polystyrene board 8 is an extruded polystyrene board, both sides of the thermal-insulating net rack board are painted with an interface agent, the internal side of the thermal-insulating net rack board is supported by a steel rack 3, a concrete cushion block 10 is placed on the external side of the thermal-insulating net rack board, the steel meshes 7 and the rebar 11 form a steel net rack to be implanted into the thermal-insulating net rack board and the external concrete layer; an auxiliary fixation rod 1 (equivalent to "a connector" in the present patent) extends through the thermal-insulating net rack board and a wall structure rebar 6, the auxiliary fixation rod 1 is linear-shaped or L-shaped, the bending end of the L-shaped auxiliary fixation rod 1 is in contact with an external template 9; the concrete cushion blocks 2, 10 are attached with a binding wire to facilitate the binding of the steel meshes 7, the rebar 11 and the wall structure rebar 6.

The PRB concluded that claim 1 differs from Attachment 1 in the following aspects: (1) claim 1 claims that interface mortar layers are disposed between the thermal-insulating board and the internal concrete layer, as well as the external concrete layer, and the external side of the thermal-insulating board is covered by the interface mortar layer, whereas Attachment 1 discloses that both sides of the thermal-insulating net rack board are painted with an interface agent; (2) claim 1 claims that a groove is disposed in one or both sides of the thermal-insulating board; (3) claim 1 claims that the external side of the thermal-insulating board is provided with concrete or mortar cushion blocks, whereas Attachment 1 only discloses that a concrete cushion block is placed on the external side of the thermal-insulating net rack board; (4) claim 1 claims the steel wire net rack is connected with a connector, and the connector is welded or anchored to the steel wire net rack; (5) claim 1 claims the connector is a structural rebar with ends in the shape of a ram's horn, 丁 or L; (6) claim 1 claims the thermal-insulating board is selected from the group consisting of an expanded polystyrene board, an extruded polystyrene board, a phenolic foam board or an inorganic thermal-insulating board, whereas Attachment 1 discloses the extruded polystyrene board. The differences (1), (3), (5) and (6) are readily conceivable; the difference (2) is of common knowledge in the art, and it can easily occur to a person skilled in the art to arrange a groove in one or two sides of the thermal-insulating board so as to make them better combined; and the difference (4) is the well-known technique that can be conceived by a person skilled in the art. In summary, the technical solution of claim 1 can be arrived at by a person skilled in the art on the basis of Attachment 1 in conjunction with the common knowledge in the art, thereby lacking inventive step. The first-instance court approved of the PRB's decision.

The second-instance court stated that the holistic principle shall be abided by when assessing the inventive step of a patent. In the present case, regarding the difference (1), although Attachment 1 discloses that both sides of the thermal-insulating net rack board are painted with an interface agent, evidence and statements presented by Jingda Co. do not suffice to prove that the mortar interface agent is an interface material commonly used in the art and it's ability to strengthen the binding between the thermal-insulating board and the concrete layer is of common knowledge in the art; meanwhile, regarding the difference (2), the thermal-insulating board and the concrete layer can be better combined by disposing a groove at one or two sides of the thermal-insulating board; regarding the difference (3), although Attachment 1 has disclosed that a concrete cushion block is placed on the external side of the thermal-insulating board, the technical solution of claim 1 of the present patent substitutes the mortar cushion block for the concrete cushion block out of a comprehensive consideration, in order to guarantee the thickness of the rebar protective layer and prevent the thermal-insulating board from being deflected outwards under the inside pressure during the casting of the concrete; regarding the differences (4), (5) and (6), the thermal-insulating layer and the wall body are built up simultaneously, which reduces the construction steps, and meanwhile achieves the purpose of keeping the service life of the thermal-insulating layer and that of the wall body equal. As can be seen, the technical solution of claim 1 of the present patent does not result from a simple combination and superposition of Attachment 1 with common knowledge. Instead, it is written for solving the technical problem to be addressed and for improving the thermal-insulating effect and fire-proof performance, facilitating wall construction and rendering the service life of the thermal-insulating layer and that of the wall body equal. To obtain the

technical solution disclosed in claim 1 based on Attachment 1 in conjunction with the common knowledge is not obvious to a person skilled in the art. Hence, claim 1 of the present patent has substantive features and progresses, thereby possessing inventive step.

Consideration shall be given to whether a technical feature and other technical features work jointly in determining whether the technical effect of the technical feature is within expectation

Account shall be taken of whether a technical feature and other technical features work jointly when determining whether the technical effect of the technical feature is identical with or similar to the prior-art effect, and whether that technical effect can be anticipated by a person skilled in the art. Under the circumstances where a plurality of technical features exerts their own functions respectively and the technical effect co-generated by the plurality of technical features is a simple superposition of their respective technical effects, the change of the technical effect arising from the change of each technical feature is expectable by a person skilled in the art. Under other circumstances where a plurality of technical features works together to jointly attain a technical effect that is not a simple combination of technical parameters and effects thereof, a change of any technical feature may give rise to an unexpected alteration in the resultant technical effect jointly achieved by those technical features.

In *Ji'an Group Co., Ltd. (Ji'an Co.) v. PRB & Shandong Century Sunshine Paper Group Co., Ltd. (Century Sunshine Co.)* [3], namely an administrative dispute over invalidation of an invention, the patent at issue is an invention entitled "coated white-top kraft linear board and manufacturing method thereof" and owned by Century Sunshine Co. Ji'an Co. submitted a request with the PRB for declaring the present patent invalid. Upon examination, the PRB decided to maintain the validity of the present patent. The first-instance court emphasized that the product of the present patent and that of Attachment 1 are classified under the same category. Claim 1 of the present patent lacks inventive step over Attachment 1 in view of Attachment 3 and common knowledge, and claim 2 of the present patent also lacks inventive step over Attachment 1 in view of Attachment 3 and common knowledge.

The second-instance court deemed that consideration shall be given to whether a technical feature and other technical features work jointly when determining whether the technical effect of the technical feature is identical with or similar to the prior-art effect, and whether that technical effect can be anticipated by a person skilled in the art. In the present case, there is no evidence proving that pigment ratios in the second coated layer and the third coated layer are in a linear relationship with such technical effects as the smoothness, gloss, whiteness and ink absorption of different cardboard pulp. Nor do the prior art and experimental data in the description of the present patent reflect the law of change of those factors. Accordingly, a person skilled in the art is unable to expect the influence of the pigment ratios in the second coated layer and the third coated layer on the technical effect. The ruling of the first-instance court deciding that the relationship between the pigment ratios in the second coated layer and the third coated layer and the technical effect can be anticipated by a person skilled in the art is factually and legally groundless.

Determination of reverse teaching

Reverse teaching is a very important factor to be considered in assessing obviousness. Where the prior art provides a reverse teaching, it is usually deemed that a person skilled in the art will head for a direction opposite to the patent in dispute. In this sense, the presence of a reverse teaching can usually prove that the patent in dispute is inventive. However, if there is explicit evidence proving that a person skilled in the art will do a search along the direction of the present patent in an effort to improve the closest prior art and obtain the claimed invention, for instance, the prior art has mutually contradictory teachings, it is still possible to determine the present patent as lacking in inventive step.

In *Bayer Pharma Aktiengesellschaft (Bayer) v. PRB & Zhao Weixing* [4], namely an administrative dispute over invalidation of an invention, the patent at issue (No. 00815054.0) is an invention entitled "pharmaceutical combination of ethinylestradiol and drospirenone for use as contraceptive" and owned by Bayer. Claim 1 of the present patent at the time of issuance reads "1. A pharmaceutical composition for oral administration comprising, as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the composition, of from about 2 mg to 4 mg, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of from about 0.01 mg to 0.05 mg, together with one or more pharmaceutically acceptable excipients or carriers, wherein said drospirenone has a surface area of more than 10,000 cm2/g." Zhao Weixing submitted a request with the PRB for

declaring the present patent invalid.

The PRB concluded that claim 1 of the present patent differs from Evidence 1 in that it does not disclose the technical feature that "drospirenone is micronized". According to the distinguishing technical feature, the technical problem to be solved by the present invention is to provide a pharmaceutical preparation with faster dissolution rate and better bioavailability. First of all, micronization is one of the conventional simple methods for improving the drug dissolution rate and enhancing the drug efficacy and has been proved to be common knowledge possessed by a person skilled in the art. Thus, a person skilled in the art is motivated to apply the means of micronization to some insoluable drugs, like drospirenone in the present patent, in order to increase the dissolution rate and furthermore improve the bioavailability. However, drospirenone is known to be acid liable and the in vitro test shows that drospirenone isomerizes into an inactive form under acidic conditions. Thus, if drospirenone for oral administration is micronized, micronization will enhance its dissolution rate in the gastrointestinal tract, which may lead to two completely different results: on the one hand, a higher dissolution rate will result in an increase in an absolute absorption rate in the gastrointestinal tract, thereby raising the bioavailability; on the other hand, micronization will also speed up the isomerisation in an acidic environment, thereby decreasing the bioavailability. Thus, micronization is not effective in increasing the bioavailability of all drugs. For each drug, whether the bioavailability can be enhanced by way of micronization relies on a series of factors, such as the dissolution performance, digestion and absorption thereof in the gastrointestinal tract. Second, the information disclosed in Evidences 11 and 13 also tells us that spirorenone is closely associated with drospirenone in terms of structure and characteristics. The latter is in fact an in vivo metabolite of the former. The only difference therebetween is a double bond. Both of them are acid sensitive at similar rates and isomerize under acidic conditions as proved by the in vitro experiments. Although spirorenone serves as a diuretic in Evidences 11 and 13, the in vivo metabolism of an oral drug will not be affected by its usage, but only by the structure, as well as physical and chemical properties, thereof. It is within the expectation of a person skilled in the art that spirorenone and drospirenone can be metabolized and absorbed in vivo similarly. Under the teachings explicitly provided by Evidences 11 and 13 that spirorenone will isomerize when exposed to acid in vitro, but will not do so in vivo, and micronization has been shown to work on absorption of spirorenone, a person skilled in the art can obviously envisage that drospirenone will have an identical or similar metabolic process (namely, it will not isomerize in vivo), and micronization is a viable option to solve the absorption issue. At last, in response to Bayer's questions about oral water load and opinions that non-detection does not mean non-occurrence and the general rule for pharmaceutical R&D is in vitro test first and in vivo test second, the PRB stated that although oral water load in Evidence 11 may help raise the pH of the gastric juice, it is still in an acidic environment; and moreover, judging from the result of "non-detection of isomerization", a person skilled in the art can reasonably comprehend that result means no isomerisation in vivo, or the extent of isomerisation in vivo is too tiny to be detected as compared with the one in vitro. On the basis of the experimental results presented in Evidences 11 and 13, a person skilled in the art is able to make a reasonable expectation that, contrary to the in vitro simulated acidic environment, drospirenone to be taken orally will not isomerize in vivo and shall be micronized for better absorption. In view that Evidences 11 and 13 disclosed spirorenone can be micronized to increase the bioavailability and spirenone to be taken orally will not isomerize in vivo, a person skilled in the art will anticipate that drospirenone can be micronized to increase the bioavailability and drospirenone to be taken orally will not isomerize in vivo. Under such teachings, a person skilled in the art has the motivation to micronize drospirenone in Evidence 1 to thereby arrive at the technical solution of claim 1 of the present patent, and the technical effect of better dissolution rate and increased bioavailability is also expectable. Accordingly, claim 1 of the present patent over Evidences 1, 11 and 13 in view of common knowledge has neither prominent substantive features nor notable progress, thereby lacking inventive step. The PRB decided to declare the present patent wholly invalid. The first-instance court concluded that the present patent is grantable due to its inventive step and ruled to revoke the Decision appealed.

The second-instance court held that the reasoning of the PRB is untenable for the reasons as follows: first, it is well-known that micronization can increase the dissolution rate of a poorly soluble drug and thereby enhance its bioavailability. Micronization of a drug that is unstable when exposed to acid will lead to a higher dissolution rate in the gastrointestinal tract, thereby decreasing the bioavailability.

Two completely different results will be seen if a poorly soluble drug that is unstable when exposed to acid is micronized, namely, on the one hand, a higher dissolution rate will result in an increase in an absolute absorption rate in the gastrointestinal tract, thereby raising the bioavailability; on the other hand, micronization will also speed up the isomerisation in an acidic environment, thereby decreasing the bioavailability. For those reasons, in vivo metabolism and absorption are the factors that must be taken into account when enhancing the bioavailability by micronizing the poorly soluble drug that is unstable when exposed to acid. Second, Evidence 11 discloses two identical characteristics between spirenone and drospirenone: (1) they are of the same composition except for a double bond, and spirorenone is an in vivo active metabolite of drospirenone; and (2) both of them are unstable as to acid-catalyzed isomerization of lactone rings in vitro. Meanwhile, Evidences 11 and 13 also provide three different characteristics between spirenone and drospirenone: (1) difference in acid sensitivity: at room temperature, it needs about 90 minutes to isomerize drospirenone in half and about 150 minutes to isomerize spirenone in half, that is, drospirenone isomerizes at a faster rate than spirenone; (2) difference in in-vivo metabolism: accumulation of spirenone in vivo is not obvious, whereas drospirenone accumulates in vivo greatly; and (3) difference in dissolution rate: the dissolution rate of spirenone is less than 5g/ml, which is lower, and the dissolution rate of drospirenone is about 15.1g/ml, which is threefold as much as that of spirenone. At last, Evidences 11 and 13 explicitly indicated that since spirenone and drospirenone are both acid-sensitive, they will isomerize in vivo. According to common sense, under the same acidic conditions, the same drug will react similarly despite in vivo or in vitro. The experimental condition of Evidence 11 is "oral water load" (3250ml every 12 hours), which will surely dilute the gastric juice, lower stomach acid and increase gastric pH, thereby decreasing the isomerisation rate of acid and reducing isomerized products. The experimental condition of Evidence 13 is "no food taken since last night" (namely "empty stomach"), under the condition of which medicament will speed up stomach evacuation. The shorter the medicament stays in the stomach, the less the poorly soluble medicament can be dissolved, and the less isomerized products it will produce. The factors such as "oral water load" and "empty stomach" will affect the in vivo isomerisation of spirenone and the detection of isomerized products. The experimental results of Evidence 11 only demonstrate that "no rearranged product of lactone resulting from spirenone is detected in the blood", without analyzing the reasons for non-detection, let alone drawing an affirmative conclusion that no isomerisation occurs. As known from the above analysis, in view of the differences between spirenone and drospirenone in acid sensitivity, in vivo metabolism and dissolution rate, the PRB erred in concluding that drospirenone has an identical or similar metabolic process (i.e., isomerisation does not occur in vivo) merely according to the negative experimental results of spirenone ("no rearranged product of lactone resulting from spirenone is detected in the blood") under certain conditions ("oral water load" and "empty stomach"), and in further deeming that a person skilled in the art can obviously realize that drospirenone shall be micronized to solve the problem of limited absorption, which lacks factual basis.

Technical solution with no technical effect described cannot act as the closest prior art in assessment of inventive step of a patent

In assessing inventive step during the course of patent invalidation, conclusion shall be drawn from the perspective of a person ordinarily skilled in the art and with comprehensive consideration given to the prior art disclosed in reference documents, which means the holistic status of the prior art, as well as the technical solutions disclosed in the reference documents, should be taken into account. A reference document shall disclose a complete technical solution. A technical solution is a combination of all technical means used for solving the technical problem under the natural law, which shall include the entirety of technical features that constitute the technical solution and meanwhile disclose the technical effect of the technical solution that can be acquired or expected by a person skilled in the art. If a person skilled in the art is incapable of acquiring or anticipating the technical effect of the technical solution, then the technical solution cannot serve as the reference document for assessing the inventive step. In addition, account shall be taken of whether there is likelihood of combining the reference documents together in assessing the obviousness. If some reference document teaches away from the present patent, it is usually deemed that the prior art does not provide any related teachings.

In *Novo Nordisk AS v. PRB & Ganlee Pharmaceutical Co., Ltd. (Ganlee Co.)* [5], namely an administrative dispute over invalidation of an invention, the patent at issue

(No.97195648.0) is an invention entitled "insulin preparations containing NaCl" and owned by Novo Nordisk AS. Ganlee Co. submitted a request with the PRB for declaring the present patent invalid, and upon examination, the PRB declared the present invention wholly invalid. The first-instance court stated that as compared with the monomeric insulin analog solution disclosed in example 12 of Evidence 6, the technical solution relating to a halogenide in claim 1 of the present patent is distinguishable in that the solution of the present patent comprises 5 to 100mM of a halogenide. As known from the distinguishing technical feature, the technical problem to be solved is to reduce the formation of desamido insulin in the solution and decrease the percentage of insulin dimers and polymers, so as to obtain stable aqueous insulin preparations. Evidence 4 is related to the influence of excipients on the chemical stability of insulin. With reference to Fig. 1 of Evidence 4, as the concentration of NaCl increases, the content of desamido insulin decreases quickly and will be at the lowest level when there is about 30mM of NaCl. If the concentration of NaCl remains at the range from 30mM to 120mM, desamido insulin is relatively low, which means that desamido of insulin is not strong and the insulin products are more stable. Under this teaching, a person skilled in the art will have the motivation to combine Example 12 of Evidence 6 with Evidence 4 to obtain more stable insulin products. Since the concentration range of NaCl that keeps insulin products stable in Evidence 4 overlaps with the concentration range (namely, 5mM to 100mM) of a halogenide in claim 1 of the present patent to a great extent, a person skilled in the art is able to arrive at the concentration range of halogenide in claim 1 under the teachings of Evidence 4 through logical analysis or finite experiments. Thus, the technical solution is obvious. Accordingly, the technical solution relating to halogenide of claim 1 of the present patent has neither prominent substantive features nor notable progress over Example 12 of Evidence 6 in view of Evidence 4, thereby lacking inventive step. For similar reasons, claims 2 to 5 lack inventive step as well.

The second-instance court held that the aqueous insulin preparation of the present patent comprises human insulin, an analogue thereof and/or a derivative thereof, which constitutes a whole technical solution. Example 12 of Evidence 6 discloses the process for preparing Asp(B28)-human insulin analog-protamine crystals, which comprises the three steps of preparing Asp(B28)-human insulin analog solution, preparing proptamine solution, and mixing the two solutions for crystallization. According to the testimony of an expert witness at the court of original jurisdiction, Asp(B28)-human insulin analog solution prepared in Example 12 is only an intermediate solution. Those skilled in the art all know that the function of Asp(B28)-human insulin analog solution as an intermediate solution is merely for further crystallization, and there is no prior-art evidence proving that the intermediate solution has a certain efficacy. The court of original jurisdiction held that the monomeric solution can be directly applied to clinics and is objectively a final product of the insulin analog. However, this is only a presumption that can be supported by no evidence. In fact, it is well-known to a person ordinarily skilled in the field of pharmaceutics that any pharmaceutical preparation used for clinics shall meet strict requirements on quality, and the closest prior art solution acting as the starting point of the inventive step assessment shall be the preparation whose pharmaceutical activity has been sufficiently proved, rather than the intermediate that is presumed to be pharmaceutically active.

Based on the above analysis, the PRB made a wrong finding of fact by comparing the monomeric insulin analog solution disclosed in Example 12 of Evidence 6 acting as the reference document with the present patent. Although the monomeric insulin analog solution disclosed in Example 12 of Evidence 6 can serve as the reference document, comprehensive consideration shall be given to the reference documents in assessing the inventive step. Having read the process for preparing Asp(B28)-human insulin analog solution disclosed in Example 12 of Evidence 6, a person skilled in the art can hardly anticipate the efficacy of the solution, let alone have the motivation to research and develop the aqueous insulin preparation of the present patent based on Example 12 of Evidence 6. Moreover, a person skilled in the art will take the technical content disclosed in Evidence 6 into full consideration during the course of reading. Surely, they will take notice of the conclusion on "effect of ionic strength on $Lys^{B28}PrO^{B29}$-hI protamine crystallization" in Example 5, namely, the increase of NaCl concentration will affect $Lys^{B28}PrO^{B29}$-hI protamine crystallization, and the higher the concentration, the poorer the crystallization. Since Evidence 6 teaches away from the use of NaCl, a person skilled in the art would not be motivated to use NaCl in Evidence 6. Although Evidence 4 provides a teaching that NaCl within a certain concentration range will stabilize the

insulin products, a person skilled in the art still would not be inspired to combine Example 12 of Evidence 6 with Evidence 4 because Evidence 6 teaches away from using NaCl. Hence, the PRB erred in finding that the technical solution relating to halogenide of claim 1 of the present patent has neither prominent substantive features nor notable progress over Example 12 of Evidence 6 in view of Evidence 4. The technical solution relating to halogenide of claim 1 of the present patent possesses inventive step, and other claims dependent on claim 1 are inventive as well.

II. Administrative patent litigation proceedings and burden of proof

The PRB shall follow the request principle and the hearing principle in the patent invalidation proceedings

The request principle and the hearing principle shall be abided by in the invalidation proceedings. *Ex officio* examination can be conducted under special circumstances without being bounded by the scope and reasons of the request submitted by the invalidation requestor. In the patent invalidation proceedings, if the PRB stands in violation of the statutory procedures because of not following the request principle and the hearing principle, the decision made thereby after examination shall be deemed as procedurally illegal.

In *Squibb Bristol Myers Co. (Squibb Co.) v. PRB & Nanjing Runnuo Biotechnology Co., Ltd. (Runnuo Co.)* [6], an administrative dispute over invalidation of an invention patent, the patent at issue (No.02821537.0) is an invention entitled "lactam-containing compounds and derivatives thereof as factor Xa inhibitors" and owned by Squibb Co. Runnuo Co. submitted a request with the PRB for declaring the present patent invalid on the grounds that the claims at issue lack inventive step.

The PRB concluded that claim 1 of the present patent seeks to protect 32 specific compounds. Evidence 1 discloses nitrogen containing heterobicycles that are useful as factor Xa inhibitors or derivatives thereof or pharmaceutically acceptable salts thereof, and they are useful as anticoagulants for the treatment or prevention of thromboembolic disorders in mammals (see page 3, lines 1-15; page 266, lines 3-5 of the Chinese translation of the description). It is found through comparison that the compounds of a general formula in Evidence 1 have covered the structures of all the compounds listed in claim 1, except 2-dimethylamino-N-{1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxo-piperidin-1-yl) phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridin-3-yl methyl}-N-methylacetamide (hereinafter referred to as compound 29) and 2-dimethylamino-N-{1-(4-methoxyphenyl)-7- oxo-6-[4-(2-oxo--2H-pyridin-1-yl)phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo[3,4 - c]pyridine 3 - ylmethyl} acetamide (hereinafter referred to as compound 30). Except compounds 29 and 30, the rest compounds claimed in claim 1 differ from those in D1 in that claim 1 claims a plurality of specific compounds, and the technical problem to be actually solved by claim 1 is to provide the specific structures of the compounds having a factor Xa inhibitory activity. Example 99 of Evidence 1 discloses 1[4-Methoxyphenyl]-3-trifluoromethyl-6-[(4-aminomethyl)phenyl]-1,4,5,6-tetrahydropyrazolo-[3,4-c]pyridine-7-one trifluoroacetic acid salt, the parent ring of which is similar to that of the compounds of claim 1 with the only difference in the substituent in the 4-position on the rightmost phenyl ring (namely, A ring), wherein the substituent in claim 1 is  (hereinafter referred to as B ring) whereas the substituent in the corresponding position in Example 99 of Evidence 1 is –CH3-NH2. Furthermore, R1a in Example 1043 of Evidence 1 is CONH2, A is phenyl and B is 1-pyrrolidinocarbonyl. The compound in Example 1043 of Evidence 1 is different from that of the present patent only in the structure of B ring. Therefore, Evidence 1 actually provides the following teaching: based on the structure of the nitrogen containing heterobicyclic formula as disclosed in Evidence 1, the compounds obtained by replacing the groups such as A, B, G and Z with the groups disclosed in Evidence 1 can still have a factor Xa inhibitory activity. Examples 99 and 1043 of Evidence 1 are the specific compounds of the above general formula and having a structure similar to that of the compounds in claim 1 of the present patent. Having read the limitation (including oxo-piperidin-yl or pyridin-yl) to groups on the B ring in the formula, a person skilled in the art will have the motivation to replace the B ring of the compounds in Examples 99 and 1043 of Evidence 1 with =O substituted piperidinyl or pyridinyl, thereby arriving at the specific compounds in claim 1, which is obvious to a person skilled in the art. Moreover, preferable compounds recited in Evidence 1 have a Ki of 1μM (see page 267, lines 20-25 of the description), and Squibb Co. stated that the compounds in claim 1 also have a Ki of ≤1μM. Through comparing the compounds of the present invention and those in Evidence 1 in the aspect of

efficacy, we found that the present patent and Evidence 1 adopt the same method for testing the activity of compounds and describe the test results in the same way. Recapitulative depiction on the test results does not suffice to prove that the compounds claimed in claim 1 of the present patent attain unexpected technical effects over the compounds of Evidence 1. Accordingly, claim 1 over Evidence 1 has neither prominent substantive features nor notable progress, thereby lacking inventive step under Article 22.3 of the Patent Law as of 2000. In summary, the PRB decided to declare the patent at issue invalid, which was upheld by the first-instance court.

The second-instance court deemed that according to the Request for Invalidation and Recording of Oral Hearing, the invalidation requestor, Runnuo Co., requested that Examples 66, 99 and 1043 of Evidence 1 shall be used as the closest prior art for comparative analysis and during inventive step assessment of claim 1 of the present patent. However, as recited in pages 18 to 20 of the Invalidation Decision, the compounds of general formula are taken as the closest prior art in assessing the inventive step. In the compounds of general formula, G may be 4-Methoxyphenyl, s is 0; A may be phenyl; B may be piperidinyl or pyridinyl replaced with 0-2 R4a, wherein R4a is selected from H, =O, and etc.; Z may be CR1a, wherein R1a is selected from –(CH2) r-R1', OCH2R1", etc.; R1' is selected from H, Br, (CF2)rCF3, C(O)R2c, C(O)NR2R2a, and the group comprising N, O and S 1-4 heteroatoms 5-10 membered heterocyclic ring system, R1" is selected from the group comprising H, etc., R2, R2a and R2c is selected from the group comprising H, C1-6 alkyl, CF3, etc., R4a is selected from the group comprising H, C1-4 alkyl, etc., and r is selected from 0, 1, 2 and 3. The PRB failed to provide evidence or make reasonable explanation to prove that the above general formula is merely a generalization of Examples 66, 99 and 1043 presented by Runnuo Co. Hence, the PRB's approach changed the manner of comparing the technologies in the inventive step assessment proposed by the invalidation requestor, Runnuo Co. The change in the manner of comparing the technologies may affect the generalization of the distinguishing technical features, determination of the technical problem to be solved by the patent at issue and the judgment on teachings. The PRB changed the comparing manner *ex officio* without explaining relevant conditions or asking the interested parties for comments beforehand, which is legally groundless. The PRB made a decision against Squibb Co. without providing any opportunities to the parties concerned to make observations on whether the present patent is inventive based on the new comparing manner, which stood in violation with the hearing principle. ■

(Written by Liu Xiaojun, reviewed by Yang Boyong)

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[1] See the Administrative Judgment No. Gaoxing(zhi)zhongzi 2948/2014 (the judges of the Panel were Liu Hui, Liu Qinghui, Jiao Yan, and the handling judge was Liu Qinghui) and the Administrative Judgment No. Yizhongzhixingchuzi 1737/2014.

[2] See the Administrative Judgment No. Gaoxing(zhi)zhongzi 615/2015 (the judges of the Panel were Pan Wei, Kong Qingbing, Shi Bisheng, the handling judge was Pan Wei, and the author was Tao Jun) and the Administrative Judgment No. Yizhongzhixingchuzi 4137/2014.

[3] See the Administrative Judgment No. Gaoxingzhongzi 1108/2014 (the judges of the Panel were Liu Hui, Shi Bisheng, Tao Jun and the handling judge was Shi Bisheng) and the Administrative Judgment No. Yizhongzhixingchuzi 1822/2013.

[4] See the Administrative Judgment No. Gaoxing(zhi)zhongzi 2684/2014 (the judges of the Panel were Xie Zhenke, Yuan Xiangjun, Zhong Ming, and the handling judge was Yuan Xiangjun) and the Administrative Judgment No. Yizhongzhixingchuzi 896/2013.

[5] See the Administrative Judgment No. Gaoxingzhongzi 42/2014 (the judges of the Panel were Jiao Yan, Cen Hongyu, Kong Qingbing, and the handling judge was Jiao Yan) and the Administrative Judgment No. Yizhongzhixingchuzi 2737/2012.

[6] See the Administrative Judgment No. Gaoxing(zhi)zhongzi 62/2015 (the judges of the Panel were Liu Hui, Liu Qinghui, Wu Bin, and the handling judge was Liu Qinghui) and the Administrative Judgment No. Yizhongzhixingchuzi 2985/2013.