Claim Construction, Doctrine of Equivalents and Estoppel

Legal Effect of Patent Prosecution History with Comments on the Supreme People's Court's Review of Wushi Pharmaceutical (No. Mintizi 20/2009)

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Wushi Pharmaceutical (No. Mintizi 20/2009) is one of the selected cases for persuasive guidance by the Supreme People's Court for its 2010 Annual Report on Trial of IP Cases. Of particular legal significance in the case is the legal role of patent prosecution history in claim construction, determination of equivalents, and the application of estoppel. Drawing mainly on the Supreme People's Court's Judicial Interpretation of Several Issues Relating to Application of Law to Trial of Cases of Dispute Arising from Patent Infringement (hereafter, the Patent Infringement Interpretation) (No. Fashi 21/2009), this article makes a comprehensive analysis of and comments on this case. Before delving into details, the writerI first gives an overview of the pertinent facts of the case and the opinions on the above legal issues written by the courts of first instance and second instance, and the reviewing court, namely, the Supreme People's Court.

I. Summary of the case

The patent in suit

In 1995, Kong Yanping filed an application with the Patent Office for a patent for the invention entitled "a drug for prevention and treatment of calcium loss and deficiency and a method for preparation of the same". In 1997, the patent application was published, and claim 1 thereof went as: "a drug for prevention and treatment of calcium loss and deficiency, said drug consisting by weight of: soluble calcium 4-8 units, zinc gluconate 0.1-0.4 units; glutamine or glutamic acid 0.8-1.2 unites." The terms "soluble calcium" and "glutamine" or "glutamic acid" are at the issue in the case. "Soluble calcium" was defined in claim 2 of the application, which was dependent upon claim 1: "a drug for prevention and treatment of calcium loss and deficiency according to claim 1, said soluble calcium is calcium gluconate, calcium chloride, calcium lactate, calcium titanic acid or active calcium." On page 2 of the description, it is recited that "for the soluble calcium, calcium gluconate, calcium chloride, calcium lactate, calcium titanic acid or active calcium may be selected".

Upon substantive examination, the examiner considered in the first Office Action that the claims were not materially supported by the description. In his view, the generic concept "soluble calcium" used in the claims covered a variety of soluble calcareous substance with a wide scope of protection, but the description only presented the embodiments of preparation of the drug with "calcium gluconate" and "active calcium", without giving embodiments showing the ingredients and effect of the other soluble calcium. Thus, it would be difficult for a person skilled in the art to foresee whether preparation made of other soluble calcium according to the invention would have the same effect in human body. For this reason, the examiner required the patent applicant to amend the claims.

The applicant amended the claims as required in the Office Action. In 2000, the State Intellectual Property Office granted the patent (ZL95117811.3) (hereafter '811 patent). In the patent as granted, "soluble calcium" was no longer recited in claim 1. The claim, as published, read: "a drug for prevention and treatment of calcium loss and deficiency, said drug consisting by weight of: active calcium at 4-8 units; zinc gluconate at 0.1-0.4units; glutamine or glutamic acid at 0.8-1.2units." And claim 2, also amended and no longer defining "soluble calcium", but only the form of the dosage, read as the following: "a drug for prevention and treatment of calcium loss and deficiency according to claim 1, said drug being in the form of powder or oral solution."

Opinion of the Court of First Instance

In April 2006, Kong Yanping, the patentee, concluded an exclusive license with the Aonuo Pharmaceutical Co., Ltd. (Aonuo). In October of the same year, Aonuo found that Hubei Wushi Pharmaceutical Industry Co., Ltd. (Wushi) made "Calcium Zinc Gluconate Oral Solution", the specifications of which read "10ml: calcium gluconate at 0.6g, zinc gluconate at 0.03g and lysine hydrochloride at 0.1g". Aonuo sued Wushi in the Shijiazhuang City Intermediate People's Court in Hebei Province, accusing Wushi of infringing the '811 patent.

On the basis of an appraisal report, the court held that the technical features of the "Calcium Zinc Gluconate Oral Solution" was equivalent to the '811 patent, and there was infringement by equivalents. Furthermore, the court rejected Wushi's argument that the doctrine of estoppel should be applicable. The court took the view that this doctrine should not apply to all the amendments and observations made during the patent prosecution. Only those materials to the Patent Office in deciding upon the novelty or inventiveness of the claimed invention could be relied upon for the application of the doctrine of estoppel. In the present case, the patentee amended the claims according to the Office Action by changing the "soluble calcium" into "active calcium" in the independent claim. In doing so, the applicant did not amend the claim to secure novelty or inventiveness, but for the purpose of support from the description for the claims. In its holding, the court concluded that the doctrine of estoppel was not applicable to those amendments.

Opinion of the court of second instance

Dissatisfied with the above decision, Wushi appealed to the Hebei Province Higher People's Court. Affirming, the court of appeal alluded three reasons for finding infringement by equivalents: 1) there is an embodiment of the "calcium gluconate" preparation in the description of the '811 patent. For a person skilled in the art, it was obvious that "calcium gluconate" and "active calcium", if prepared according to the claimed invention, would have the same effect in human body. The two were not substantially different when used as a raw material for preparing calcium supplement, being equivalent and substitutable; 2) in the appendix of the Notice of Reassessment Results of Local Drug Standards for Respiratory System, Vitamins and Mineral Material (No. Guoyaoguanzi 131/2000) issued by the State Drug Administration on 10 April 2000, it was directly indicated that lysine hydrochloride 10g might be substituted for glutamic acid 10g for making the "Zinc And Calcium Oral Solution (the product made by Aonuo); and 3) the appraisal report relied on by the court below reliably indicated that the "active calcium" was equivalent to "calcium gluconate", "glutamic acid or glutamine" to "lysine hydrochloride". Accordingly, the court of appeal found Wushi infringing.

As for whether the doctrine of estoppel should apply, the court of appeal concur with the court below, holding that the amendments were made to secure support from the description for the claims, not to lend novelty or inventiveness to the patent, precluding the application of estoppel.

Opinion of the Supreme People's Court

Dissatisfied again with the decision of the appeal, Wushi petitioned the Supreme People's Court to allow certiorari review of the case. At the end of 2008, the Supreme People's Court allowed this petition (No. Minshenzi 458/2008).

First, the court held that the contested term "active calcium" mentioned in claim 1 did not cover "calcium gluconate". In its view, it was quite clear from claim 2 and page 2 of the description of the published application that "said soluble calcium was calcium gluconate, calcium chloride, calcium lactate, calcium titanic acid or active calcium", thus "calcium gluconate" and "active calcium" were two parallel concepts of isolatable soluble calcium, the former not subsumed under the latter. Moreover, embodiment 1 of the description of the published application of the patent in suit involved calcium gluconate as the raw material, and embodiment 2 active calcium as the raw material. This fact further showed that the two terms "calcium gluconate" and "active calcium" were parallel to each other, the former being not a subclass of the latter.

Aonuo, however, contended that during the prosecution, the applicant amended "soluble calcium" into "active calcium" merely for the purpose of clarification that "active calcium" covered all calcium, including calcium gluconate. The Supreme People's Court rejected this argument as untenable. The Court pointed out that the patent prosecution history showed that the patentee's amendment was directed to the SIPO's Office Action. There, the examiner took the position that the term "soluble calcium" in the claims of the published application of the patent in suit was too broad to be supported by the description. Furthermore, the applicant did not mention that the term "active calcium" covered "calcium gluconate" in his observations made in response to the Office Action. For these reasons, the Supreme People's Court did not entertain Aonuo's argument.

Second, the Supreme People's Court ruled that "active calcium" was not equivalent to "calcium gluconate" on the ground of the "doctrine of estoppel". The Court took the view that the patentee who surrendered a technical solution by amending, or observations, directed to the claim and the description might not reclaim it in subsequent patent infringement litigation. The patentee amended claim 1 during the patent prosecution and surrendered the technical solution having the technical feature of "calcium gluconate". The corresponding technical feature of the allegedly infringing product was "calcium gluconate", being the technical solution surrendered. Accordingly, the court held that they should not be deemed to be equivalents; the accused product should not be considered falling within the scope of the protection of the patent in suit.

Third, the Supreme People's Court ruled that "glutamine or glutamic acid" and "lysine hydrochloride" constituted no equivalents mainly on the ground of the prosecution history of another patent granted to Aonuo. The application of that patent was filed on 19 February 2003, entitled "an oral solution for prevention and treatment of calcium loss and deficiency and a method for preparation of the same". It was granted the patent ZL 03104587.1(hereinafter '587 patent). Independent claim 1 of '587 patent and claim 1 of the patent in suit were similar, except for "lysine hydrochloride" of the former replacing the "glutamine or glutamic acid" in the latter. Specifically, claim 1 of '587 patent read as the following: "an oral solution for prevention and treatment of calcium loss and deficiency, said drug consisting by weight of: soluble calcium 4-9 unites; zinc gluconate 0.1-0.4 unites; glutamine or glutamic acid 0.8-1.2 unites". During the patent prosecution, Aonuo made the observations that compared with the formula of zinc gluconate mixing with glutamine or glutamic acid, the formula of the zinc gluconate mixing with lysine hydrochloride had an unexpected effect for calcium gluconate oral solution in physio-chemic property, and there was substantial progress in terms of solutability and stability of calcium gluconate. To substantiate this observation, Aonuo presented relevant test data.

The Supreme People's Court took the ground that the SIPO granted '587 patent in reliance upon the above observation that claim 1 of said patent was distinguished from claim 1 of the patent in suit for "lysine hydrochloride" in lieu of "glutamine or glutamic acid". Therefore, in terms of the patent law, "glutamine or glutamic acid" and "lysine hydrochloride" were two distinct technical features, and the two were substantially different for making zinc gluconate oral solution. The allegedly infringing product had "lysine hydrochloride", rather than "glutamine or glutamic acid" in claim 1 of the patent in suit. For these reasons, the Court held the "glutamine or glutamic acid" and "lysine hydrochloride" were not equivalents.

In addition, the Supreme People's Court noted that although the appendix of the above State Drug Administration's Notice (No.Guoyaoguanan 131/2000) said that "lysine hydrochloride at 10g might be substituted for glutamine at 10g", this was merely regulatory, not meaning that the two were interchangeable in the sense of the patent law. This may not serve as a safe ground for finding "lysine hydrochloride"of the allegedly infringing product equivalent to "glutamine or glutamic acid" of claim 1 of the patent in suit.

In short, the Supreme People's Court concluded that the two technical features of "calcium gluconate" and "lysine hydrochloride" of the allegedly infringing product were neither identical with, nor equivalent to, the corresponding technical features of the "active calcium" and "glutamine or glutamic acid" in claim 1 of the patent in suit, and did not fall within the scope of protection for the patent in suit. The Court held that Wushi did not infringe.

II. Claim construction: legal effect of published patent application

In deciding that "active calcium" in claim 1 did not cover "calcium gluconate", the Supreme People's Court relied mainly on the published application of the patent in suit in construing that claim. Specifically, the Court noted in the judgment that it was clear from claim 2 and page 2 of the description of the published application that "said soluble calcium is calcium gluconate, calcium chloride, calcium lactate, calcium titanic acid or active calcium"; and that embodiment 1 of the description of the published application of the patent in suit involved calcium gluconate as the raw material, and the embodiment 2 active calcium as the raw material.

Thus arises the legal issue: What is the legal role of a published application for interpreting a claim of a granted patent? It should only play a secondary part, relative to the claims and the description and the drawings of a patent. First, under the Chinese Patent Law, the extent of protection for a patent is determined by the claims of the granted patent and the description and drawings may be used for explana-

tion. [1] There is no provision for patent prosecution history (including the published application) for claim construction. Second, the Patent Infringement Interpretation also shows that relative to the claims and description of the granted patent, patent prosecution history should only be secondary for claim construction. Article 2 thereof provides that courts "shall" determine the meaning of the claims by their terms in the light of the understanding by a person skilled in the art mindful of the description and drawings (of the granted patent). In this connection, Article 3 thereof further provides that the courts "may" explain the claims by the description, drawings, other claims and patent prosecution history. It is thus clear that patent prosecution history is not a must for claim construction, but rather optional, depending on the circumstances surrounding the case. In sum, patent prosecution history should be secondary and supplementary for the purpose of claim construction.

This is so because of the following basic legal fact: the Patent Office grants patent only when the examiner is satisfied that the application, from the eyes of a person having the ordinary skill in the art, meets all the statutory requirements. For this purpose, the final text of the application, which is later published as grant, governs, rather than the published application, which is only the starting point and subject to amendments during prosecution. Furthermore, the patent as granted serves as a public notice showing to the public the coverage of the granted patent. Within the patent as granted, there is credibility of the patent office, and public reliance. They deserve respect. Therefore, the text of the granted patent (including the claims and description) should be the primary evidence in claim construction.

In the present case, the Supreme People's Court does not have to go so far as to rely on the published application to interpret the claim in question. Actually, it is clearly mentioned on page 2 of the description of the patent as granted that "said soluble calcium is calcium gluconate, calcium chloride, calcium lactate, calcium titanic acid or active calcium". Moreover, embodiment 1 of the description involved "calcium gluconate" as raw material, and embodiment 2 "active calcium" as raw material. From these places, a person skilled in the art could reasonably see that the term "active calcium" of claim 1 did not cover "calcium gluconate".

Besides, while the description of the patent in suit covered the invention involving calcium gluconate as raw material, the applicant did not claim it. The Supreme People's Court could have accordingly held that the patentee had "dedicated" that invention to the public. In this connection, the Article 5 of the Patent Infringement Interpretation provides that where a technical solution is described in the description and the drawings, but not claimed, the rightholder may not reclaim it in a subsequent infringement action.

Finally, if the Court had relied on the patent as granted to construe the claim, Aonuo's following argument would have been very weak: during the prosecution, the applicant amended "soluble calcium" into "active calcium" merely for the purpose of clarification that "active calcium" covered all calcium, including calcium gluconate. The reason is simple: a claim should be interpreted through the eyes of the person skilled in the art. This is objective. Even if the applicant's true intention was to "make clarification" in amending Claim 1, this does not govern because it is a subjective intention within the mind of the applicant only.

III. Doctrine of estoppel: legal effect of amendment to claims

Regarding the issue whether "active calcium" and "calcium gluconate" were equivalents, the Supreme People's Court actually applied the so-called "doctrine of estoppel" provided for in Article 6 of the Patent infringement Interpretation. According to this provision, where an applicant or a patentee surrendered a technical solution through amendments to the claims or the specification, or statements made in the examination or validation procedures, the right holder shall not be permitted to reclaim it as part of the protection of the patent in a subsequent infringement action. This stands in sharp contrast with the doctrine of estoppel provided for in the Beijing Higher People's Court's Opinions on Several Issues Concerning Patent Infringement Adjudication (Tentative) (No. Jinggaofafa 229/2001), eliminating the restriction that the "doctrine of estoppel" is confined to amendments made to avoid novelty or non-obviousness destroying prior art. Article 43 of the Opinions provides: "a patentee who narrowed or partially surrendered the scope of the protection for the claims in order to secure novelty or inventiveness of his patent in examination, revocation or invalidation procedures through written statements or amendments to the specification, and on this account, obtained the patent, must not recapture what he has delimited, excluded, or surrendered by using the doctrine of equivalents in a later infringement action." [2] Obviously, the courts of first and second instance was relying on this provision when they decided that the doctrine

of estoppel must not apply to the amendment made to secure support of the description for the claims. The Supreme People's Court, however, relying on Article 6 the Patent Infringement Interpretation, arrived at the judgment that the "doctrine of estoppel" was applicable to "surrendered technical solution", regardless of whether the technical solution was surrendered to secure novelty or inventiveness or not.

This expansion has sound legal basis. A patent is granted only when the claimed invention meets not only novelty and inventiveness requirements, but also other statutory requirements, including sufficiency of disclosure. After an applicant amends the application, the amended application serves as the basis for the examiner's decision as to whether the application meets all the statutory requirements for granting patent. This fact compels the conclusion that the "doctrine of estoppel" should apply to any amendments and observations made by an applicant to make the application compliant with those requirements for patent grant. This was the reason for the US Supreme Court to have taken a similar approach in the famous Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.[3].

It must be noted, however, that the Court only held in Wushi that the "doctrine of estoppel" applies to "surrendered technical solution". This holding does not place any limitation upon the patentee to claim protection under the doctrine of equivalents for any amended claim, contrary to the position taken by CAFC in Festo.[4] There, CAFC held that in narrowing claims to secure a patent, the patentee has therefore given up all the equivalents of the amended elements, and may not reclaim patent protection for those equivalents. CAFC took the view that in consciously amending original claims, the applicant knew the difference between the original claims and the amended claims, and thus could foresee the territory he had surrendered. The US Supreme Court granted certiorari, holding that amendment to patent application is not absolute bar to subsequent claim against infringement under the doctrine of equivalents.[5] But the US Supreme Court also recognised that when amending claims, the applicant should have a better idea about the scope of the claims. For this reason, the US Supreme Court held that the "patent applicant's decision to narrow his claims through amendment may be presumed to be general disclaimer of territory between the original claim and amended claim." [6] Distinct from this position, Wushi only concerns surrendered technical solution. Therefore, under the current Chinese patent system, a patentee enjoys protection for equivalents to elements in claims unless it is proved that he "surrendered" them. Amendment as such does give rise to complete or presumptive bar to protection against infringement under the doctrine of equivalents.

Under the Chinese patent system, the key issue for application of estoppel turns upon how to determine "surrender". In Wushi, the Supreme People's Court, when determining "surrendered" technical solution, did not require proof of the patentee's intent. Should subjective intention be the necessary condition for determining "surrender". The court would have to examine in detail the proceedings before the patent office in order to establish the applicant's intention in amending the claims. All the circumstances surrounding the case should have been considered, for example, the particular applicant's, or his patent agent's, experience with patent prosecution. If that was the law, where the patentee later proved that he had no intent to surrender, the court would have no ground to find that the applicant had "surrendered" owing to negligence. In Wushi, the Supreme People's Court opined that "for the same reason as to whether the term 'active calcium' covers 'calcium gluconate', the patentee surrendered the technical solution of using 'calcium gluconate' as the raw material, and thus the 'doctrine of estoppel' should apply. Thus, it was through claim construction that the Supreme People's Court found "surrender". As the claims are required to be interpreted through the eyes of the person skilled in the art, the Supreme People's Court must take the view that "technical solution surrendered" should be determined against the same notional person standard, [7] a position distinct from "abandonment" of a civil right.

Meanwhile, however, there arises another legal issue: Does Article 6 of the Patent Infringement Interpretation provide for a rule for claim construction doctrine, or for the "doctrine of estoppel"? In Wushi, the final judgment recited the "doctrine of estoppel" and copied the entire provision without citation of Article 6. In so doing, however, the judgment did not mention whether "active calcium" and "calcium gluconate" were equivalents. At the same time, in Wushi, the final judgment made it clear that the reasoning behind its finding of surrender was "for the same reason as to whether the term 'active calcium' covered 'calcium gluconate'", pointing to its construction of claim 1 where it was determined that through amendment to that claim during prosecution, the patentee surrendered the technical solution involving the technical feature of 'calcium gluconate'. This opinion of the Court may gain support from Article 7 of the Patent In-

fringement Interpretation. According to it, the extent of protection for a patent is determined both by literal infringement and infringement under the doctrine of equivalent. As a result, the surrendered inventions may not be reclaimed in these two cases. An ostensibly reasonable conclusion from Wushi might be drawn as the following: Article 6 of the Patent Infringement Interpretation is a rule both for claim construction, applicable to literal infringement; and for "estoppel", applicable to infringement under the doctrine of equivalents.

But it should not be so, viewed in the light of the whole structure of the Patent Infringement Interpretation. Article 6 should only be interpreted as a rule for "estoppel". With regard to claim construction, patent prosecution history should only be used as a secondary evidence to explain the meaning of the terms in the claims. As discussed in section II, this is what laid down in Article 3 of the Patent Infringement Interpretation. Only when a given term as properly interpreted could not cover a particular technical feature is it possible for a patentee to claim it as an equivalent under the doctrine of equivalents by invoking Article 7, paragraph two, of the Patent Infringement Interpretation.[8] Only when an equivalent otherwise protectable was "surrendered" during the patent prosecution in narrowing statement or amendment might it give rise to "estoppel". In this event, Article 6 should be applied. Were Article 6 treated as a rule for claim construction, then Article 3 would have been rendered redundant to a considerable extent. Thus, the precondition for invoking Article 6 is a finding of equivalents under the doctrine of equivalents.

IV. Equivalency: legal effect of prosecution history of subsequent patent

Regarding the issue of whether "glutamine or glutamic acid" and "lysine hydrochloride" were equivalents, the Supreme People's Court said no, relying primarily on the prosecution history of '587 patent. This patent was filed and granted subsequent to the patent in suit. Actually, as the exclusive licensee of the patent in suit, Aonuo filed its application for '587 patent three years after the patent in suit had been granted. Here a legal issue arises from Wushi: to what extent the statement by the licensee of a given patent in prosecuting a subsequent patent may be used as evidence for the purpose of limiting the protection for the earlier one under the doctrine of estoppel?

First of all, the patent prosecution history of a patent subsequent to the grant of the patent in suit may not give rise to "estoppel" simply because during the examination of the earlier patent, the examiner could not be reasonably expected to know—and rely on—the statements made by an applicant in response to an Office Action from the Patent Office with regard to a later patent. In this event, the patentee cannot be reasonably presumed to have "surrendered", through such statements for the later patent application, a technical solution claimed in the earlier one. However, the judgment of Wushi strongly stressed Auno's observations made during the examination of '587 patent and specified that "the Patent Office granted '587 patent in reliance of the observations". It appears that the Court was applying "doctrine of estoppel". But it should be noted that Aonuo was not the applicant of the patent in suit, but only a licensee thereof; Aonuo filed the application for '587 patent several years after the patent in suit was granted, which was not the object of the present case. For a reasonable court, Auno's observation made in the examination of the subsequent patent application should not have been deemed to give rise to estoppel, but as evidence for finding non-equivalent between "glutamine or glutamic acid" and "lysine hydrochloride".

With the Wushi judgment so interpreted, the above legal issue should be reformulated as the following: what's the evidentiary role of a subsequent related patent and its prosecution history in finding equivalents to a feature recited in a claim of an earlier patent?

Before going into depth of this issue, it is necessary to understand the legal rule for determining equivalents and the reference point of time under the Chinese patent system. According to Article 17, paragraph two, of the Supreme People's Court's Several Provisions on Issues Relating to Application of Law to Trial of Cases of Patent Disputes (2001), an equivalent to a given feature recited in a claim must use substantially the same means, perform substantially the same function, and produce substantially the same effect with regard to that feature, and can be associated by a person having ordinary skill in the art without undue burden. It should be noted that this "triple identity" test suitable for analysing mechanical devices, it often provides a poor framework for analysing other products or processes.[9] For this reason, in Wushi, the Supreme People's Court concerned itself with whether "glutamine or glutamic acid" and "lysine hydrochloride" were "substantially different". As for the reference point of time for finding equivalents, there is no express provision in the current judicial interpretations. The

only authority is Article 37 of Opinions on Several Issues Relating to Patent Infringement Adjudication (Tentative) (No. Jingaofafa 229/2001), which provides that "whether a technical feature of the allegedly infringing article (product or process) is equivalent to a technical feature in the independent claims of the patent in suit should be evaluated at the time of infringement." Given the influence of these Opinions within the Chinese judiciary and relevant international practices, [10] it may be presumed that Wushi endorsed the same approach. Thus, the Court was facing the following issue: at the time of the infringement, whether "glutamine or glutamic acid" and "lysine hydrochloride", as involved in the claimed invention and the accused product, have no substantial difference (i.e. interchangeable equivalents" [11]) such that they could be associated by a person skilled in the art without undue burden? If the answer is yes, they are equivalents. Otherwise, they are not.

With the legal issue so framed, it is easy to know the evidentiary role of the patent prosecution history of '587 patent. In terms of rules for evidence, the prosecution history of '587 patent and the SIPO's grant decision thereupon are two different sorts of evidence, the former being factual, and the latter expert opinion. The test data presented in Auno's observations made in the examination of the '587 patent might be evidence used for determine whether "glutamine or glutamic acid" was substantially different from "lysine hydrochloride" in view of the patent in suit. Auno's observation is an opinion of her own, being of little value as to the understanding of a person skilled in the art at the time of the infringement as to equivalency of the said elements. Further, this opinion was made outside the pending litigation, and thus might not be treated as "admission" against the Plaintiff Auno. Last, the SIPO's decision to grant '587 patent might at best be regarded as "expert opinion" in respect of the test data and relevant scientific evidence presented by Aonuo. It must be admitted that the SIPO was assured that the application satisfied all the statutory requirements for patent grant, not in reliance upon Aonuo's opinion—"compared with the formula of zinc gluconate mixing with glutamine or glutamic acid, the formula of the zinc gluconate mixing with lysine hydrochloride had an unexpected effect for calcium gluconate oral solution in physio-chemic property" —but on its understanding of the test data and relevant scientific evidence as presented by Aonuo. This specialist opinion should be considerably probative，even if it was not made at the time of infringement for the purpose of evaluating equivalency. In combination with other evidence, for example, the Appendix (in which was revealed substitution of lysine hydrochloride at 10g for glutamic acid at 10g) of the Notice (No. Guoyaoguanan 131/2000) issued by the State Dug Administration, if the Court considered that they may prove that at the time of infringement, whether "glutamine or glutamic acid" and "lysine hydrochloride", as involved in the claimed invention and the accused product, had no substantial difference such that they could be associated by a person skilled in the art without undue burden, then it may find them not equivalents. Otherwise, they are. ■

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[1] Article 59 paragraph one, of the Patent Law of P.R. China: The extent of protection for a patent for invention or utility model shall be determined by the terms of the claims. The description and the appended drawings may be used to interpret the content of the claims.

[2] In the amendment to these Opinions circulated for comments, this provision has changed a great deal. See Article 54 of the Draft of the Opinions on Several Issues Relating to Patent Infringement Adjudication issued for comments (April 2011): By the doctrine of estoppel is meant that where during the patent prosecution or invalidation procedure, a patentee narrows, or surrenders a part of, the claims through written statement, or amendment made to the application or the patent, the court hearing infringement action must not allow the patentee to recapture what he has delimited, excluded, or surrendered by using the doctrine of equivalents in a later infringement action. Article 56: The doctrine of estoppel should applies only when the following conditions are met: (1) the narrowing or surrendering of the relevant technical features by a patent applicant or patentee must be explicit in the patent documentation, valid and final decision of validity or administrative decisions; and (2) the technical content so narrowed or surrendered must have material effect on the grant or maintenance of the patent.

[3] 535 U.S. 722 (2002).

[4] 234 F.3d 558 (Fed. Cir. 2000).

[5] 535 U.S. at 740-741(A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim. There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the

patentee could not reasonably be expected to have described the insubstantial substitute in question.)

[6] Ibid.

[7] Cf. Insituform Technologies, Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1107-08(Fed. Cir. 1996) (In examining the prosecution history in an estoppel analysis, we do not look to the subjective intent of the applicant and what the applicant subjectively believed or intended that he or she was giving up to the public. ... Rather, the standard for determining what subject matter was surrendered is objective and depends on what a competitor, reading the prosecution history, would reasonably conclude was given up by the applicant).

[8] Article 7 of the Patent Infringement Interpretation: When determining whether the allegedly infringing technical solution falls within the extent of protection for the patent, the people's court shall examine all the technical features of the claims asserted by the right holder. Where the allegedly infringing technical solution contains technical features identical with or equivalent to all the technical features of the technical solution, the people's court shall rule that said technical solution fall within the extent of protection for the patent; where compared with all the technical features of the claims , one or more technical features of the claims are missing in the allegedly infringing technical solution, or one or more technical features are not identical or equivalent, the people's court shall rule that said technical solution does not fall within the extent of protection for the patent .

[9] See Warner-Jenkinson Company, Inc., v. Hilton Davis Chemical Co., 520 U.S. 17, 39-40 (1997).

[10] See, e.g., Warner-Jenkinson Company, Inc., v. Hilton Davis Chemical Co., 520 U.S. 17, 37-38 (1997).

[11] See Article 35 of the Opinions on Several Issues Relating to Patent Infringement Adjudication: "Equivalents shall be interchangeable between technical features, not between two technical solutions as a whole."