Product by Process Claim: Extent of Protection and Infringement Determination

Comments on Youta Corp. v. Wangao Corp. (No. Mintizi 158 (Supreme People's Court of China, 2010)

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Youta Corp. v. Wangao Corp. is one of the cases selected by the Supreme People's Court for the Annual Report on Exemplary IP Cases (2010). 1 Those elected cases are intended to provide persuasive guidance for courts at the lower level to adjudicate IP cases. This case raises concerns at least about the following legal issues: the extent of protection of a product by process claim, application of estoppel doctrine, and the evidentiary rules for determining infringement of a production process. In this article, the writer will be expounding all the issues, and the article will start with an overview of the relevant facts and legal opinions.

I. Summary of the Case

1. The Patent in suit

On 20 April 2004, Youta Corp. (Youta) filed, with the State Intellectual Property Office (SIPO), an application for a patent for the invention relating to Lamiophlomis Rotata (hereafter "LR") soft capsule and its preparation process. Independent claim 1 of this patent was in dispute. In the published patent application, the claim read as follows:

"A LR soft capsule preparation, wherein said capsule consisting by weight of: LR extract 20-30 units, vegetable oil 25-36 unites, and suspending agents 1-5 unites."

After the substantive examination, the examiner made the first Office Action. In response, Youta amended Claim 1, observing that:

"This applicant has amended claim 1 in response to the Office Action. As a result, 'LR extract' in claim 1 is defined by the four methods described in the description. These four methods are the product of many an experiment and testing. They are not part of the prior art. Therefore, the LR extract made by these methods is not equivalent to the prior art recited in Part 1 of the Drug Code of the People's Republic of China (2000 ed.) ."

On 10 May 2006, this application was allowed (Patent No.200410031071.4) (hereafter '071 patent'). Claim 1 as granted read as follows:

"A LR soft capsule preparation, wherein said capsule consisting by weight of: LR extract 20-30 units, vegetable oil 25-36 units, and suspending agents 1-5 units;

Said LR extract is prepared in any one of the four methods: I. LR medicinal herb, crushed into coarse powder (technical feature B1), and then decocted with as twice as much water. For the first time, the water being 10-30 times by weight and the time for decocting being 1-2 hours; for the second time, the water being 10-20 times by weight and the time for decocting being 0.5-1.5 hours (B2); combining the medicinal liquid, filtering it, then letting the filtrate to concentrate into thick paste (B3); then drying the paste in low pressure environment and crushing it into fine powder; and sifting the powder through 200 mesh sieves (B4). II ··· "

Importantly, the LR extraction method in claim 1 was specifically described in the description. In the section entitled "Best Extraction Conditions" on page 12 of the description, it was said that compared with three-time-decoction, two-time-decoction was better for the sake of reducing production costs. And in the section entitled "Embodiment 5: Powder Fineness" on Pp.15-16 of the description, it was said that the composition was most stable of the soft capsule comprising LR fine powder sifted through 200 mesh sieves.

2. Opinion of the Court of First Instance

In February 2007, Youta launched a lawsuit before the Chengdu Intermediate People's Court, alleging that Wangao Corporation (Wangao) infringed '071 patent' by making and selling the Kaigao brand "LR soft capsule" without authorisation, and that Kelun Corporation infringed the same patent by selling the product so made.

During the trial, Wangao filed a request with the Patent Reexamination Board of SIPO (PRB) for declaring the patent in suit invalid. The validity of the patent was upheld by the PRB, its reviewing court of first instance and second instance. For the purpose of the follow-up discussion, it is worth mentioning that as for the element "sifting through 200 mesh sieves" in Claim 1, Youta made specific observations during the oral hearing before PRB. According to Youta, its study on particle size of LR extract showed that the fine powder sifted through 200 mesh sieves had the largest sedimentation rate, and the composition of LR soft capsule so made was most stable; "LR soft capsules had the following advantages over LR capsules: ... in the preparation for LR soft capsule, LR extract was crushed into fine powder and then sifted through 200 mesh sieves." Furthermore, in Decision No. 11005, the PRB pointed out that

"Claim 1 comprises preparation method I which has distinctive technical features not disclosed in reference 1 and reference 2, such as, 'crushing LR medicinal herbs into coarse powder', 'adding water and decocting the mixture twice', adding '10-30 times of' water for the first time, adding '10-20 times of water' for the second time, and 'crushing the thick paste into fine powder and sifting it through 200 mesh sieves'. The claimed invention is an optimised method for extracting LR: the selected times of decocting and amount of water added would increase the extract yield and the amount of the effective ingredient Luteolin; crushing the thick paste into powder and sifting it through 200 mesh sieves would achieve much better sedimentation rate. As a consequence of this optimised process, the claimed invention is superior to the dosage form in the prior art in that the soft capsule has smaller dosage, quicker disintegration inside intestines-stomach, better absorbent, shorter onset time, higher bio-usage, and more stable preparation."

In the first-instance trial, Youta did not obtain any evidence of Wangao's process for making the accused product. At the request of Youta, the court took as evidence from the State Food and Drug Administration's (SFDA) Drug Approval Document No. Guoyaozhunzi Z20050221, including the Standard YBZ 08242005 (tentative) and documents submitted by the Jiangsu Chenpai Drug Co., Ltd. for drug approval concerning process for preparing the "LR soft capsule" (hereinafter collectively referred as "the Documented Process"). In the Documented Process, the method for extracting LR read as follows:

"Taking LR raw medicinal herb 1000g, crushing it (technical feature b1); adding 10 times of water and decocting three times, an hour for each time (b2); combining the liquid upon decoction of herbs, filtering it, condensing the filtrate into thin paste with a density of 1.30 (b3); drying the paste at 80°C, grinding it into fine powder for further process (b4)".

Wangao raised no objection to Youta's assertion that the accused product was identical with the patented product in terms of dosage form, composition and ingredient proportion, but argued that the process for extracting LR was different from the corresponding features in Claim 1.

In the court's view, Claim 1 of '071 patent' was a product claim characterised by process features. It claimed a soft capsule product consisting of LR extract, vegetable oil and suspending agents at a defined proportion, with LR extract being prepared by any one of the specified four methods. The features b1-b4 in the Documented Process were equivalent to features B1-B4 in Claim 1 respectively, as they used substantially the same means, performed substantially the same function, and achieved substantially the same effect, and could be acquired directly from the description of the patent without undue burden. Consequently, the court found that there was an infringement.

3. Opinion of the Court of Second Instance

Upon appeal, Wangao argued that it adopted a technology in the prior art as recited in Part 1 of the Drug Code of the People's Republic of China (2000 Ed.) (hereafter "Drug Code") with regard to LR extraction, being totally different from the method recited in Claim 1, let alone being equivalent to it. However, the court held a different opinion. In the court's view, Wangao's process was different from the Drug Code both in the proportion of water added for decoction and in the additional feature as to fine powder crushed from dried substance. Further, in the court's view, while in the substantive examination, Youta made restrictive amendment to the original claim in response to the Office Action, that is, narrowing LR extraction to its preparation methods, and argued in the follow-up invalidation procedure that the LR extraction method described in '071 patent' was not disclosed

in the prior art, Youta only abandoned the technical solution comprising the dosage form, composition and ingredient proportion: the technical solution of the accused product did not fall within what Youta abandoned. Accordingly, the court upheld application of estoppel doctrine.

Moreover, Wangao also argued that the accused product did not have the features of "reduced pressure" and "sifting through 200 mesh sieves" in Claim 1. In the court's view, Claim 1 was a product claim comprising process features. In the pharmaceutical industry, production process was often confidential, inaccessible to a complaint. In the present case, Youta requested the court to take the Documented Process as evidence, showing that Wangao's accused technology bore identical or equivalent parts with regard to the patented technology. However, the Documented Process was not a complete one, being silent as to the specific method of drying and mesh size for sifting. During all the proceedings, Youta requested several times that Wangao provided its records of batch production of the accused products and the regulatory GMP application documents. But Wangao failed to do so within the time for producing the evidence which might have shown that its process concerning drying and sifting was different from Claim 1. As a result, the court took the view that Article 75 of the Supreme People's Court's Several Provisions Relating to Evidence in Civil Procedure (hereafter "Rules of Evidence for Civil Procedures") should be applied. According to this article, where one party withholds disadvantageous evidence and refuse to produce it without justification, the court may presume a corresponding fact asserted by the other party. Accordingly, the court held that b4 and B4 were presumptively equivalents.

4. The Supreme People's Court's opinion

Dissatisfied with the second-instance decision, Wangao requested the Supreme People's Court to grant writ of certiorari. The Supreme People's Court found that while the Documented Process comprised only the element "grinding into fine powder for use" without mentioning "sifting 200 mesh sieves", the Part 1 of the Drug Code provides that the "ground fine powder" referred to powder sifted through 80 mesh sieves. Besides, Wangao produced the records of batch production of Chenpai Drug when it requested for writ of certiorari. The Court considered this evidence as further "corroboration" that there was no further step of sifting through 200 mesh sieves beyond having sifted through 80 mesh sieves. The Supreme People's Court held that the court of the lower levels erred in applying Article 75 of the Rule of Evidence for Civil Procedures on the ground that the Documented Process taken from SFDA was incomplete. It was erroneous to find on presumption that "grinding into fine powder" and "crushing into fine powder and then sifting through 200 mesh sieves" were equivalents.

Meanwhile, the Supreme People's Court pointed out that even if Wangao did not actually make the accused product according to the Documented Process, the court below should have issued an order to preserve evidence, for example, conducting site inspection or seizing the production records according to the Civil Procedure Law and the Patent Law, rather than made a simple presumption in reliance on Article 75 of the Rule of Evidence for Civil Procedures.

Having removed the evidentiary base of the reviewed judgment, the Supreme People's Court then focused on Youta's observations made during the prosecution and invalidation proceedings. Specifically, the Court pointed out that: (1) Youta emphasised in these proceedings that "the four methods of the present invention for preparing said LR extract were products after a lot of work was done on screening and testing. They were not disclosed in the prior art. Said LR extract in the claimed invention was not equivalent to the prior art, that is, the LR extract in Part 1 of the Drug Code"; (2) In the section entitled "Best Extraction Conditions" on page 12 of the description, it was read that compared with three-time-decoction, two-time-decoction was better for the sake of reducing production costs; and in the section entitled "Embodiment 5: Powder Fineness" on Pp. 15-16 of the description, it was read that the composition was most stable of the soft capsule comprising LR fine powder sifted through 200 mesh sieves. For these reasons, the Supreme People's Court decided that "decocting twice" was not equivalent to "decocting three times", "crushing into fine powder, sifting through 200 mesh sieves" not equivalent to "grinding into fine powder", citing Article 17 of the Supreme People's Court's Several Provision on Issues Relating to Application of Law to Trial of Cases of Patent Dispute as of 2001 (the Patent Dispute Interpretation) and Article 6 of the Supreme People's Court's Interpretation of Several Issues Relating to Application of Law to Trial of Cases of Disputes over Patent Infringement as of 2009 (the Patent Infringement Interpretation).

II. Extent of protection for a product by process claim

In the present case, the first-instance and second-instance courts both held that Claim 1 was a product claim characterised by process features. The Supreme People's Court did not give its opinion on this matter. When evaluating infringement, the three courts all proceeded with the method for preparing LR as recited in Claim 1. As a result, the Supreme People's Court failed in this case to address the two prerequisite legal issues: Is Claim 1 a product by process claim? If yes, what should be the legal principle to determine the scope of protection for this sort of claim in infringement litigation?

To begin with, under the Chinese patent system, a product-by-process claim is allowable in patent prosecution. but it is viewed as a product claim in essence. In the Explanation of Several Issues in Trying Administrative Disputes over Patent Reexamination and Invalidation, the Beijing Higher People's Court in 1999 pointed out that "normally, product claims apply to product inventions. They should be defined and described by structural features. Only when it is impossible to define the invented product by its structural features, or doing so would render the claim unclear, it is permissible to characterise the product claim in terms of process features."

The current Patent Examination Guidelines as of 2010 (hereafter PEG) takes a similar view: "where one or more technical features of a product claim cannot be clearly defined by either structural features or other parameters, it is permissible to characterise that feature or features in terms of process steps. However, the subject matter of such a claim is still 'product' "2.

Thus, when evaluating novelty and inventiveness of this sort of claims, it is not the process features that count, but the features of the product obtained from the process governs.3

Claim 1 of '071 patent' included the process for preparing LR extract, a component of the LR soft capsule. Is it thus a product-by-process claim? The answer is not as direct as it appears. Attention should be paid to the following facts. In response to the first Office Action, Youta stated that "this applicant has amended claim 1 in response to the Office Action. As a result, "LR extract" in the claim 1 was defined by the four methods described in the description". Youta also emphasised that "these four methods are the product of many an experiment and verification test. They are not part of the prior art." By stressing the preparation process for LR extract, rather than the LR extract as such,

the patent applicant in fact did not claim absolute protection for LR raw mendicant (as the components of the "LR soft capsule") obtained through any process. Rather, it confined the protection for the element to the four specific processes. Consequently, Claim 1 should not be identified as a product claim characterised by process features.

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The Technical Board of Appeal of the EPO heard similar disputes, holding that in like circumstances, the process features should be taken as limitations for the amended claims. In T423/89, the original claims specified several manufacturing processes disclosed in the description. During the patent prosecution, the rightholder amended the claims by restricting them to one of the manufacturing processes. Upon examination, the Technical Board of Appeal of the EPO held that through said amendment, the rightholder had ceased to claim absolute protection, but undertook a significant limitation of the claim.

To sum up, it is open to question that Claim 1 is a product claim characterised by process features, as it was held by the court of first and second instances. And it is thus regrettable that the Supreme People's Court did not even touch upon this legal issue, even though it is a precondition for determine the scope of protection for the claim and whether there was an infringement.

Moreover, while all the three level courts proceeded with the assumption that Claim 1 was a product claim characterised by process features, they all failed to articulate the legal principles suitable to determine the scope of protection for this sort of claim. Under Chinese patent regime, this sort of claim is treated as a product claim in patent prosecution. However, the same does not necessarily apply to patent infringement litigation. It is well accepted that process features are permissible in a product claim only when it is impossible to use structural features to define the invented product (or where the structural features cannot clearly define it). Then, how could a patentee prove that an accused product was the product defined by those process features? It must be noted that the patentee only disclosed the process for making the product, and the claims only specified that process, without disclosing the structural features of the claimed product. As a result, how could an infringement court make the necessary comparison between the accused product and claimed product? Acutely aware these legal difficulties, the United State Court of Appeals for the Federal Circuit took en banc hearing on its own initiative in Abbott Laboratories v. Sandoz, Inc., and held that "process terms in product-by-

process claims serve as limitations in determining patent infringement".4

When granting writ of certiorari, the Supreme People's Court should not concern itself too much with the justice of an individual case, but should strive to improve the operation of the legal system, in particular, by providing guidance as to murky legal issues. While Youta v. Wangao is elected as one of the model IP cases, the Supreme People's Court even failed to address the above two legal issues, which are basic and prerequisite for arriving a well reasoned judgment. And they are all of significance for the patent system. These flaws make Youta v. Wangao not so exemplary as it might be at the first glance.

III. Estoppel Doctrine

It is made clear in the Annual Report on Exemplary IP Cases (2010) that Youta v. Wangao is selected for providing guidance as to the application of Article 6 of the Supreme People's Court's Patent Infringement Interpretation (2009).⁵ The essence of this provision is that "a patentee's observations made in the patent prosecution and invalidation proceedings may lead to estoppel." The Supreme People's Court showed its preference for this provision in a series of cases it has decided recently. Whenever there is an amendment, it appears that the provision takes priority over all rules for claim construction.7 Unsurprisingly, the question arising from this case is: when a technical solution is already excluded from the scope of protection for the claimed invention by virtue of a person skilled in the art's understanding of the claim in the light of the description and drawings, is there still room for the application of the doctrine of equivalents and the doctrine of estoppel?

In Youta v. Wangao, the technical solutions comprising "decocting three times" and "grinding into fine powder" are excluded from the scope of the claimed invention in the light of Claim 1 and the description. In the section entitled "Best Extraction Conditions" on page 12 of the description, it reads that compared with three-time decoction, two-time decoction is better for the sake of reducing production costs. And in the section entitled "Embodiment 5: Powder Fineness" on Pp. 15-16 of the description, it reads that the composition is most stable of the soft capsule comprising LR fine powder sifted through 200 mesh sieves. Furthermore, according to the final judgment, "grinding into fine powder" meant the fine powder sifted through 80 mesh sieves.

It must be noted that "decocting three times" and "sifting through 80 mesh sieves" were not present in Claim 1. According to Article 5 of the Patent Infringement Interpretation, a rule for claim construction, where a technical solution is merely described in the description, but is not claimed, the patentee may not reclaim the technical solution in a later patent infringement lawsuit. And Article 7 provides that the extent of protection for a patent shall be determined by the technical features recited in the claim, or the equivalents thereto. Consequently, a technical solution disclosed in the description, if not claimed, may not be included into the scope of protection for the claimed invention by virtue of the doctrine of equivalents.

Therefore, it was totally unnecessary for the Supreme People's Court to rely on Article 17 of the Patent Dispute Interpretation, going so far as to evaluate the equivalency between "decocting twice" and "decocting three times", and the equivalency "crushing into fine powder, sifting through 80 mesh sieves" and "grinding into fine powder", let alone to consult the prosecution history and Youta's observations made in the patent invalidation proceedings in order to exclude these equivalents from protection by applying the estoppel doctrine in Article 6.

Some may counter the above proposition, arguing that "decocting twice", "grinding into fine powder, and sifting through 200 mesh sieves" flew from amendments in the prosecution and therefore the scope of protection so lost is within the meaning of "surrender" in Article 6. But it should be noted that Article 6 provides for "estoppel doctrine", which by definition is not the primary rule for determining the scope of protection for a patent. For the purpose of claim construction, it is Article 2 of the Patent Infringement Interpretation that governs. This Article provides that a competent court shall determine the scope of protection for a patent as understood by a person of ordinary skill in the art after reading the description and the drawings. Thus, only when a particular technical feature is outside the scope of protection through proper claim construction, the patentee may then seek additional protection by resort to the doctrine of equivalents in order to include that feature into the scope. And only when the equivalent was "surrendered" by the patent applicant during the patent prosecution, the alleged infringer may resort to the doctrine of estoppel in order to prevent such inclusion of the equivalents. Therefore, when a technical solution is already excluded from the scope of protection for the claimed invention by virtue of proper claim construction,

there is no room for applying the doctrine of equivalents to include it into the scope and then to apply the doctrine of estoppels to excluded it from the scope once again. Article 5 of the Patent Infringement Interpretation, as a rule for claim construction, already offers a simple way out: where a technical solution is disclosed in the description, but it is not claimed, such technical solution is not part of the scope of protection for the patent.

In addition, the tribunal of this case took a position quite different from the tribunal in Dalian Xinyi Building Material Co., Ltd. v. Dalian Rendaxin New-type Wall Material Plant (Xinyi v. Rendaxin), even though the two three-person tribunals have the presiding judge and another judge in common. In that case, the claim of the utility model patent in suit read as follows: "a thin concrete barrel member, comprising a barrel pipe and barrel bottoms which seals the holes at the ends of the pipe, characterised in that said barrel bottom is made of at least two or more layers of fiber cloth affixed together ... ". The barrel bottom of accused product, however, had only "one layer of fiber cloth", other technical features being identical with those in the above claim. Both the firstinstance and second-instance courts found infringement on the ground of doctrine of equivalents. The Supreme People's Court took the view that according to the Chinese Patent Law, the scope of protection for an invention patent or utility model patent shall be determined by the terms of the claims, and the description and the drawing may be used to interpret the claims. The claim in suit is framed as "at least two or more layers ... " layers of fiber cloth, a term being "crystal clear", and the description also clearly read that fiber cloth of the barrel may be "as few as only two layers". Therefore, "at least two or more layers" should be viewed as a limitation on the claim. Consequently, the Supreme People's Court refused to apply the doctrine of equivalents.

The lesson from this case is simple: where a claim is defined in clear terms, they are limitations of the claim and may not be vitiated in claim construction or by virtue of the doctrine of equivalents. *Youta v. Wangao* has facts similar to this case, and by analogy, this lesson should apply. In *Youta v. Wangao*, "decocting twice" is a crystal clear term in Claim 1 of '071 patent'. And in the section entitled "Best Extraction Conditions" on page 12 of the description is stressed that "decocting twice" is distinct from "decocting three times". Thus, "'decocting twice' in Claim 1 of '071 patent' is as clear as "at least two layer of fiber cloth" in the building material patent. This term should be an effective limitation of the

claim and must not be vitiated through claim construction or the application of the doctrine of equivalents. This same line of reasoning applies to "crushing into fine powder and sifting through 200 mesh sieves" and "grinding into fine powder". Consequently, the doctrine of equivalents should not apply, let alone the estoppel doctrine provided in Article 6 of the Patent Infringement Interpretation.

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The above analysis shows that the Supreme People's Court took two totally different line of reasoning in *Xinyi v. Rendaxin* and *Youta v. Wango*. While China is not a case law country, the reason for the Supreme People's Court to grant writ of certiorari is to improve the functioning of laws through exemplary cases. To this end, the Supreme People's Court should at least stick to the basic principle that similar cases should be treated similarly. Where the Court decides to depart from its previous holding in a like case, it is expected to make some explanations so as to give guidance to lower courts in trying similar case in the future. Regrettably, we have not seen any of these sorts of efforts in *Youta v. Wangao*.

To sum up, the judgment is not clear as to how to determine the scope of protection for claim 1. The judgment did not consider Article 5 of the Patent Infringement Interpretation, nor its own reasoning in similar cases it reviewed. It is fair to say that the Supreme People's Court failed in *Youta v. Wangao* to clarify the application of relevant provisions, and would cause even more confusion as to the relationship between the estoppel doctrine provided for in Article 6 of the Patent Infringement Interpretation and the rules for claim construction.

IV. Evidentiary rules for determine accused process

It is also made clear in the Annual Report on Exemplar IP Cases (2010) that *Youta v. Wangao* is selected for providing guidance for applying Article 75 of Rules of Evidence for Civil Procedures.⁸ However, *Youta v. Wangao* itself suffered at least two evidentiary defects: (1) belated evidence produced in requesting writ of certiorari is considered in the judgment; and (2) double standards are adopted as to Article 75 application.

Before going any further into these two defects, it is necessary to make clear the role of Documented Process in evaluating infringement in *Youta v. Wangao*. As mentioned before, the process features serve as limitations for the patent

in suit. As a result, the plaintiff should carry the burden of proof that the defendant's production process includes the steps recited in Claim 1. For this purpose, it is the process Wangao actually used that was under attack. Youta requested many times Wangao to provide the records of batch production and the filed GMP files concerning the accused product, but Wangao refused to do so. As a result, the Documented Process was used as a proxy to the accused process. The Documented Process as such is not infringing because it is no direct evidence that the defendant actually adopted that process.

Undoubtedly, the records of batch production of the accused product must be critical to find whether Wangao infringed Youta's patent. Wangao did not produce this evidence during the proceedings before the lower level courts. It produced Chenpai Drug's records of batch production when requesting writ of certiorari. The records read " ... putting the paste evenly on the baking pan to dry it in 80°C; after crushing, sifting the powders through 80 mesh sieves; taking a sample test; the qualified powders may be used for preparation or stored for future use ... " These steps directly touched upon the disputes in the proceedings below. For this late evidence, the Supreme People's Court considered in the final judgment, saying that "the records of batch production further corroborates that the accused process did not have the step 'sifting through 200 mesh sieves' beyond 'sifting through 80 mesh sieves'".

Only when the records are qualified "new evidence" should the Supreme People's Court consider it. Article 179 of the Civil Procedure Law of the People's Republic of China provides: "where there is new evidence sufficient for reversing a judgment or decision", the case shall be re-tried. However, strict requirements must be met for it to be "new evidence". In the Annual Report on Exemplar IP Cases (2009), the Supreme People's Court gave a clear guidance as to how to determine "new evidence". In Foshan City Shengfang (Lianhe) Lianhe Co., Ltd. v. Trademark Review and Adjudication Board (TRAB) of the State Administration for Industry and Commerce (SAIC) and Johnson & Johnson (hereafter "Johnson & Johnson case"), 9 the Supreme People's Court pointed out that "'new evidence' should be evidence discovered after a decision is made, or any evidence that might not have been obtained for objective reasons in the original administrative proceedings, or that could not have been produced within the specified time limit. To be accepted as "new evidence" the evidence that could have been produced in the previous administrative proceedings would make the threshold requirements for administrative procedures meaningless, to the detriments of legal order." 10 While this case mainly concerned "non bis in idem" in the administrative procedures of trademark review and adjudication, these legal opinions should also apply to judicial procedures. If a party is allowed to produce key evidence which could have been produced in proceedings below when he was requesting writ of certiorari, the first-instance and second-instance trials would be void, and the Supreme People's Court would be reduced to be the first-instance court, leaving the three-level judiciary system meaningless. In the present case, Wangao produced the Chenpai Drug's records of batch production when it requested writ of certiorari. It did not provide them either in the first-instance or the second-instance hearing. There is no indication in the final judgment that the records might not have been obtained for objective reasons in the proceedings below, or could not have been produced within the specified time limit. Therefore, it is highly dubious that they were eligible to be "new evidence".

Some may counter the above proposition, arguing that the Supreme People's Court only considered that belated evidence as "corroboration", not as "new evidence". It must be noted, however, the records were the key evidence in finding infringement in Youta v. Wangao. Considering them as "corroboration" is sufficient to produce undue prejudicial effect, eclipsing the probative value of all other evidences, and thus unduly sway the tribunal's judgment. That is, even though the records were considered as "corroboration", not as "new evidence" for granting writ of certiorari, this practice did enough harm to the established legal order already. At the same time, it is fair to say at the very least that the Supreme People's Court itself did not follow its own early practices as recited in Supreme People's Court Annual Report on Exemplary IP Cases (2009), that is, the Johnson & Johnson case.

More regrettably, the Supreme People's Court took an ambiguous attitude toward the Documented Process. On the one hand, the final judgment opined: "while the court of second instance took the Documented Process as evidence of the process for making the accused product, it refused to recognise those technical features in the Documented Process that were different from the patented ones as part of that very process, and then made a presumption by applying Article 75 of the Rules of Evidence for Civil Procedures. There is a double-standard problem, and therefore the judgment below is unconvincing."

Obviously, the Supreme People's Court was asking the court below to take the Documented Process as the sole evidence for the process for making the accused product. On the other hand, the final judgment itself did just the same thing. It treated the Documented Process as the process for making the accused product, and considered the belated evidence where there are difference between the Documented Process and the patented process. There is also a double-standard problem, and therefore the judgment is unconvincing by the same token.

Finally, the Supreme People's Court also took double standards with regard to the application of Article 75, castrating the persuasive value of Youta v. Wangao in this aspect. On the one hand, the final judgment makes clear that "the court below should have issued an order to preserve evidence, for example, conducting site inspection or seizing the production records under the Civil Procedure Law and the Patent Law, rather than made a simple presumption in reliance on Article 75 of the Rule of Evidence for Civil Procedures". On the other hand, the Supreme People's Court implicitly applied the same article in a like "simple" manner. Legally speaking, the belatedly produced evidence, the records of batch production, should not have been relied on in finding infringement or non-infringement. The Supreme People's Court was thus in a place like the courts below. It could do nothing, but rely on the Documented Process in evaluating infringement. It should be noted that it was in doubt whether the Documented Process was in fact the process adopted by Wangao. In the present case, it was an assertion by Youta that the two were the same. Wangao had the evidence for his process for making the accused product, but withheld them without justifications. During the proceedings, the Supreme People's Court neither issued an order to preserve the evidences, or to inspect the site, or seize the records of production, in order to discover the fact, nor remanded the case, ordering the court below to do the above. Rather, it simply presumed Youta's assertion as true, without even explicitly citing Article 75. When the Supreme People's Court could not act according to the rules laid down by its own, how could it be expected that the courts below may learn any guidance from Youta v. Wangao? ■

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- ¹ The Supreme People's Court's Civil Judgment No. Mintizi 158/2010.
- ² Chapter 2 of Part 2 of Patent Examination Guidelines as of 2010, P. 142.
- ³ Chapter 2 of Part 2 of Patent Examination Guidelines as of 2010, P. 161: "where a product claim is characterised by process features, the examiner should consider whether those process features can inform certain structural or composite features of the product. Where those structural or composite features are different from those in the reference through the lens of a person skilled in the art, the claim is novel."

Also see the PRB's Patent Reexamination Decision No. FS17686 made on 21 June 2009.

- ⁴ See *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (en banc).
- ⁵ Article 6 of the Patent Infringement Interpretation (2009): "where an applicant or a patentee surrendered a technical solution through amendments to the claims or the description, or statements made in the examination or validation proceedings, the right holder shall not be permitted to reclaim it as part of the protection of the patent in a patent infringement action."
- ⁶ The Supreme People's Court's Guidance on Cases of IP Adjudication, the China Publishing House of Legal System, 2010, P.13.
- ⁷ See He Huaiwen, Claim Construction, Doctrine of Equivalents and Doctrine of Estoppel: Legal Effect of Patent Prosecution History, with comments on the Supreme People's Court's Review of Wushi Pharmaceutical (No. Mintizi 20/2009), China Patents & Trademarks, 2011, Issue 3, Pp. 10-17.
- ⁸ See supra Note 6, P.72.
- ⁹ The Supreme People's Court's Administrative Judgment No. Xingtizi 2/2008.
- ¹⁰ See supra Note 6, P.146.