A "Premature Baby": Observations on the First Chinese "Bolar Exception" Case

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Introduction

Late 2006, the Beijing No.2 Intermediate People's Court rendered the first-instance ruling in the Sankyo Co., Ltd. and Shanghai Sankyo Pharmaceutical Co., Ltd. v the Beijing Wansheng Drug Industry Co., Ltd. (Wansheng for short), which (hereinafter referred to as the "Sankyo case") is regarded by Chinese legal practitioners as the first Chinese "Bolar Exception" case. In the ruling, the court held that although the defendant Wansheng had used the disputed patented process to make the disputed drug with the intention to do clinical trial and apply for approval of production, this act of making the product had been done to test the safety and effectiveness of the drug so made for the purpose of satisfying the requirements of the relevant State agency for the regulatory approval of the drug. Given that the defendant did not make the disputed drug directly for the purpose of marketing it, this act should not be characterized as using the patent for "the purposes of production and business" under the Patent Law of the People's Republic of China(hereinafter referred to as the Patent Law), and thus there is no infringement by the defendant[1]. But in fact there is neither express provision for the regulatory approval under the Patent Law, nor does the Article 11 of the Patent Law imply that there should be any legal differentiation between "directly" and "indirectly" for the making and marketing purposes. And it is well known that in the United States, Japan and Europe where the "Bolar Exception" is established, the courts did not deny that acts to obtain information for grant of regulatory approval are conducted for business purposes. The ruling was really surprising to the Chinese legal practitioners . But that case was not the end; and in August 2007, the same court made another five similar rulings in similar cases between Eli Lilly and Company and Ganli Drug Industry Co., Ltd[2]. It seems that this Chinese version of "Bolar Exception" cases is to be established. Consequently, wariness should be called upon. Some argued that the Sankyo case was a compelled choice made in dilemma[3]. But with a close examination of the Chinese legal system, one could conclude that the case was in fact not a compelled choice, but a "premature baby": the court was too forward and it should have taken a more reasonable way out of the dilemma. It will be made clear in this article that the court should either have stay the case and requested the competent authority to come up with an interpretation of Articles 11 and 63 of the Patent Law; or should have applied the "scientific research and experimental use exception" under Article 63 of the Patent Law instead of unreasonably straining the Article 11.

1. A Judiciary or Legislative Issue?

Is it appropriate for the judiciary to figure out a way out of the Bolar's legal difficulties? By introducing the new legal concept "not directly for the marketing purpose", the court has actually recognized a new sort of exception to patent rights. It should be noted that the "Bolar Exception" implicate not only the balance between the interests of pioneer drugs and those of generic drugs, but also the balance between patent right protection and new drug development. There are huge proprietary interests at stake, and thus it is a policy issue that should be addressed by legislation. It is unsuited for a court, especially a first-instance court, to make a judgment on the matter. The legal issue in the "Sankyo Case" whether it is an infringement or not to use a patent for "clinical trial and applying for approval of production" is no longer a matter of applying a specific law provision. In fact, this legal issue calls for a legal explanation either of "for the production and business purposes"[4] of the Article 11 or the "scientific research and experimental use exception" of Article 63 of the Patent Law, or both. This is a matter where "the legal provisions themselves need clarification or supplementary provision." According to the Resolution on the Enhancement of Law Interpretation adopted by the Standing Com-

mittee of the National People's Congress, this sort of matter "shall be interpreted by the Standing Committee of the National People's Congress or specified by decrees". In addition, the fact that the ongoing third amendment of the Patent Law includes such a provision like the "Bolar Exception", further shows that this matter should not to be characterized as a matter of applying a specific law provision; rather, it is a matter that should be up to the law-making body.[5]

Even if this issue could be handled judicially, only the Supreme People's Court (SPC) is in the position to make such interpretation, an act of a quasi-legislative nature. When come to matters of such significant proprietary interests, it is critical to ensure nation-wide consistency in law application. We must note that although the "Bolar Exception" is well justified, with good examples such as United States and European Union, and have survived the test of WTO Dispute Settlement [6], it is not safe to assume that Bolar Exception is such a clear rule that could be easily and simply applied. For instance, the recent U.S. case Merck KG. A. A v. Integra Lifesciences I, Ltd. gave rise to divided legal views about the proper scope of the "Bolar Exception". In that case, Integra was the patentee of five patents for a plurality of RGD peptides[7]. Merck used three RGD peptides in preclinical research to develop a new drug, and it did not apply to the Federal Food and Drug Administration (FDA) for clinical test of these three RGD peptides. Integra approached Merck, expressing its willingness to license the said patents, but Merck refused the offer. In consequence, Integra brought the lawsuit against Merck for infringement. It should be noted that unlike the corresponding traditional situation, Merck did not use the Integra's patents to make generic drugs, but rather as research tools to develop new drugs. That's why this case drew wide attention from the research tool sector.

Both the district court and the Court of Appeals for the Federal Circuit (CAFC) construed the Bolar exception provision narrowly and decided that such act constituted an infringement, holding that the otherwise infringing activity must directly produce information for submission to the FDA's safety and effectiveness approval processes. But the US Federal Supreme Court thought otherwise. The Supreme Court held that the use of patented compounds in preclinical studies is protected under §271 (e)(1) at least as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments will produce the types of information relevant to the corresponding FDA process. That is to say, §271 (e)(1) provides for a wide berth for the use of patented drugs in activities related to the federal regulatory process, including uses reasonably related to the development and submission of any information under the FDC. The case was therefore remanded to the Court of Appeals for retrial, which on remand ruled in July 2007 that Merck did not infringe the patents.

It has been more than two decades since the Hatch-Waxman Act coming into being, and the U.S. courts must be quite experienced in applying it. As the above case shows, however, tremendously divided views may arise as to the scope of its application. And finally the Federal Supreme Court's must be called upon to render interpretation on this matter.

Imagine what would have happened should this same case take place in China, a country with no counterpart to the CAFC? To date, more than 60 Chinese courts have the jurisdiction over patent infringement cases; and there is no court to hear nation-wide appeals flowing from these patent disputes. Should these courts be eager to draw on the experience of the Sankyo case, and the judges be allowed to apply "for the production and business purposes" of the Article 11 in a way as freely as showed in the Sankyo case, a wide disparity would arise across the country in law application in this matter. Consequently, the legal certainty of the patent rights would be endangered. But this undesirable situation could be prevented by a proper judiciary interpretation issued by the SPC'.

Then, what is the procedure that should be applied in the case? The court should have stayed the case, and made request for legal interpretation on the matter. While the Chinese Civil Procedure Law does not provide explicitly for this circumstance, Article 136(6) thereof provides that "other circumstance, where the procedure shall be suspended". And this may be justified by some reference to the Administrative Procedure Law. According to the Article 51 of the SPC's Interpretation of Several Issues Relating to the Implementation of the Administrative Procedure Law of the People's Republic of China [5] the procedure should be suspended "where a case implicates a matter of law application that the competent authorities should be requested for interpretation or reaffirmation". Arguably, this provision could provide important guidance as to "other circumstance, where the procedure shall be suspended" in the above article of Civil Procedure Law. In addition, the court should not issue temporary measures anymore, including temporary injunction and

property preservation; and should terminate them, if there were any. The reason is simple: Given that it is the provisions in the Patent Law themselves that should be clarified, and similar cases are all likely to be held to be non-infringing in many countries around the world, there is no solid legal basis for any temporary measures. In short, the effect of the stay suggested above may actually almost amount to that of applying "Bolar Exception" which is still in legislation[8].

2. "Not directly for the marketing purposes" versus "scientific research and experimental use exception"

If a solution must be found out within the current Patent Law , it is more appropriate to apply to the Sankyo case the "scientific research and experimental use exception" in the Article 63 of the Patent Law, rather than to strain out an awkward interpretation out of the Article 11 . First of all, as a matter of legal interpretation, the Article 11, as a general provision prescribing the scope of patent protection, should be interpreted widely. Thus, the introduction of the legal concept "not directly for the marketing purposes" may well have much bearing on patent protection as a whole in that such concept is all likely to open door to many kinds of new exceptions to patent rights. By contrast, Article 63, a provision for exceptions to the patent right, is itself subject to rather strict limitations. Any "limited expansion" of the exception is to be interpreted in a very restricted manner. That is to say, applying the latter provision to the Sankyo case must result in weak impact on patent rights. More importantly, it is recommended in the third amendment to the Patent Law that a "Bolar Exception" is to be added to the Article 63, rather than a modification of the Article 11. If it were legally acceptable that court could apply the Article 11 in the way like in the Sankyo case, it is conceivable that in the near future, courts could be very interested in seeking the legal basis for patent right limitation in Article 11, by incessantly exploring the legal differences between "directly" and "not directly" for the production and business purposes. The impact on the patent system is not hard to imagine anyway. In comparison, even though the "Bolar Exception" is added to the present patent law by the third amendment, it can be taken as a legislative interpretation of the "scientific research and experimental use exception" within the current patent law. Legal certainty will not suffer substantially.

Moreover, in terms of the judicial system, the Beijing Higher People's Court would be more inclined to support application of the "scientific research and experimental use exception". On the one hand, Opinions on Several Issues of Patent Infringement Adjudication (Tentative Implementation) (Hereinafter referred to as the Tentative Opinions) issued by the Higher Court in 2001 neither explained the term "for the production and marketing purposes", nor mentioned that acts "not directly for the marketing purposes" is outside the reach of "for the production and marketing purposes" under the Patent Law. It is thus arguable that the Beijing Higher Court thought--and thinks--that in this matter, the law is already sufficiently clear and requires no interpretation.

On the other hand, while the provision of the "scientific research and experimental use exception" under the Tentative Opinions is rather demanding, there is still considerable room for its application. The Article 98 (2) thereof provides that "'use solely for the purpose of scientific research and experiment' means use for the purposes of research in, test and improvement of others' patented technologies, with a result of new technological achievement based on the existing patented technologies". And the Article 98 (3) states that "the making or using others' patented technologies in the course of scientific research and experiment with the purpose other than research in or improvement of the technologies and with a result not directly related to the patented technologies, constitutes an infringement." While the conditions for applying this exception seem strict under this Tentative Opinions, the possibility to apply the "scientific research and experimental use exception" to cases like the Sankyo is not ruled out for reasons as following:

First, even if a 100% imitation can hardly escape liability by invoking this exception, where the drug so made is "different from" the patented drug but still falls within the bounds of the alleged patents, this could nevertheless apply. The requirement of "newness" stated as " with new technological achievement" in the Tentative Opinions is not necessarily high; and the said "improvement" should not necessarily be a big technical step forward. In view that the ruling in the Sankyo case did not indicate the technical difference between the defendant's product and the plaintiff's patent claim, it seems that this matter was not a point of dispute in the proceedings.

Second, even if there is no new technical achievement at all, if there is evidence showing that the allegedly infringing acts was carried out with the intent or plan to find new knowledge or improve the existing technology, such act should possibly fall within the "scientific research and experiment exception". Regarding qualification for this exception, Tentative Opinions requires that "a new technological

achievement" shall be produced on the existing patented technologies. This does not sound sensible. What the law shall do here is to define what act constitutes an exception to patent infringement. The results of an act should not be the only determinative factor in characterising the act at issue. This is particularly unsuited for scientific research and experiment, for these acts are expected to explore for new knowledge, in the course of which failure is all but likely. Furthermore, the disputed scientific research and experiment may be still in progress when the infringement litigation begins or is in process, and the result is nowhere to be found. How could the judge decide such a case by speculation of the possible results of this kind of disputed research and experiment? Thus, it could be accepted that if an act results in some new technical achievement, it is more likely that it is covered by "scientific research and experimental use exception"; if it does not, such act could still constitute the exception under certain conditions. It could be argued that as long as there is evidence showing that such act carries with the intent or plan to improve technology, such act should be characterized as "scientific research and experimental use" for the purpose of the Article 63 . However, the Sankyo judgment does not even allude to the intent or plan to improve the disputed technology, which shows that it failed to be a point of legal dispute between the parties.

Third, an act should not be excluded from the "scientific research and experimental use exception" merely because it is a clinical test carried out for the purpose of developing and submitting information for regulatory approval. If "new knowledge" is taken as knowledge not accessible to the public, then clinical test is an act to seek "new knowledge", and should count as an act of "scientific research and experiment". This is made clear by the German Federal Supreme Court pointed out in Klinische Versuche II[9]: the law exempts all experimental acts from patent infringement without further limitations and that therefore it does not matter whether those acts produce scientific results or results of commercial interest or whether they are directed to obtaining marketing approval in order to prepare market entry of a drug after patent expiry. The only statutory condition is that the experiments are carried out with the intention of gathering knowledge about the subject of the invention including its use in order to overcome an existing incertitude[10]. There is no reason why Chinese court could not adopt a similar approach.

Fourth, an act should not be excluded from the "scientific research and experimental use exception" merely because such scientific research and experiment is carried with a "collateral" commercial purpose or with commercialization as its end. The "scientific research and experimental use exception" strikes a delicate balance between the protection of innovation and advancing new technology; and therefore, any formal interpretation in this regard should be made with caution. Nowadays, much narrower gap exists between science and technology, and many a scientific discovery is quickly turned into applied technology. It is even hard to say that science itself is pure and carried out simply to search for new knowledge or to satisfy human curiosity. In fact, scientific research is often undertaken with a close or remote end of commercialization. It is hard for scientific research free of commercialization potential to get financed and launched. Thus, any interpretation may have impact equally on both science and technology. It should be noted that the narrowly-applied US experimental use exception has a considerable negative impact. On the average, one-sixth scientific research projects are forced to be stopped or never started as a result of the grant of patents[11]. Similar problems are in other countries. As a response, the United Kingdom Gower's IP Report issued in the late 2006 recommended that research exception should be clarified in order that research in the U. K. is not similarly impeded[12]. China is now proactively in promoting collaboration between industry and University. This legal issue will become even more outstanding. The Beijing Higher Court may keep these conditions in mind in law interpretation and application.

In addition, the Beijing Higher People's Court would not ignore SPC's inclination, as the latter have already clearly indicate its support for applying this exception. In fact, the SPC once sought to address patent dispute arising in the course of application for and approval of drugs by reference to the Article 63, which is showed by the Article 48, paragraph 2 of the Provisions on Several Issues Relating to Trial of Cases of Patent Infringement Dispute (issued in 2003 for comments). That article states that where "one make, use a patented product or use a patented process and the product obtained directly from the patented process for the purpose of clinical test, in the process of application for a drug registration making, in order to exploit the said technology immediately after the patents expire, the People's Court should deal with this sort of cases by applying the Article 63 (4), of the Patent Law. While this document has not yet been officially promulgated, it manifests the SPC's mind.

Finally, the plaintiff of the Sankyo case made an unconvincing argument that "scientific research and experimental use exception" should not apply, claiming that such application should contradict the forthcoming Bolar Exception provision. The Plaintiff relied on the legislative mode and its explanation of the Draft Amendment to the Patent Law of the People's Republic of China (the Draft Amendment for short). It was recommended in the Draft Amendment that to the Article 63(4), item (5) is to be added: "where patented drugs or patented medical appliances are made, used or imported solely for the purpose of developing and submitting information required for regulatory approval of such drug or medical appliance, and where the said patented drugs or medical appliances are made or imported and sold to the person for the purpose said above"[13], such acts shall not be deemed as infringing. It was further pointed out in the statement attached to the Draft Amendment that this provision followed the example of the US "Bolar Exception", and distinguished itself from the scientific research and experimental use exception[14].

But the above claim is not tenable. At the first place, according to the Law of Legislation of the People's Republic of China, the Draft Amendment is not even a law draft yet; and the statement concerning the legislation recommendation prepared by the State Intellectual Property Office could never be an effective interoperation of the law. At best, such statement is only of importance for making reference. Furthermore, courts shall decide cases according to the laws in force, not to concern itself with any would-be laws. As a first-instance court, the court for Sankyo case did not even have to consider the possible conflicts between old and new laws and issues of smooth transition. In any event, it shall be for the legislative body or the Supreme Court to take care of such things. And in fact, there exists no possibly material conflict at all when the court had applied the scientific research and experiment exception under the current Patent Law, even if future law dictates that the Chinese Bolar provision included in the Draft Amendment should apply to such case. Legally speaking, he amendment will serve as the "legislative interpretation" of the current scientific research and experimental use exception, that is , if both item (4) and (5) of Article 63 of the Draft Amendment take effect, they will constitute an interpretation of the current Article 63 (4), adopted by the law-making body. When the amended Patent Law comes into force, it prevails. And there is no threat to legal certainty whatsoever indeed.

Conclusion

In sum, it proves clear that the first Chinese "Bolar Exception" case is a "premature baby" because the court was rather forward. The best way was for the court to stay the case, and request the competent authority to come up with an interpretation on the Articles 11 and 63 of the Patent Law. After all, it was no longer a matter of applying specific provisions, but a policy matter where huge conflicting interests are at stake between pioneer drugs and generic drugs and patent protection and new drug development. A legislative act is needed. And the second best way is for the court to apply the "scientific research and experimental use exception" in that this was more appropriate than to boldly straining an article prescribing the general scope for patent rights and this way is more likely to be supported by the appellate court should an appeal have followed. Nevertheless, even if the "scientific research and experimental use exception" is applicable to this sort of cases, given the difference between this exception and the "Bolar Exception" --the latter has a wider scope of exemption, it is still necessary to take legislative act to establish the "Bolar Exception". In view of this delayed legislation, is the Sankyo case really premature in terms of industry development and law practicing? It could be fair to say that the "Bolar Exception" is rather a "post-mature bay" for China. ■

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[1] See the Beijing No.2 Intermediate People's Court's Civil Judgment No. Erzhongminchuzi 04134/2006.

[2] See the Beijing No.2 Intermediate People's Court's Civil Judgments Nos.13419-13423, available at http://bjgy.chinacourt.org/cpws/

[3] See Jiang Hongyi, A Compelled Choice Made in Dilemma: Comment on the Issue of Application of Law to the First Case of "Bolar Exception" in China, in the China Patents & Trademarks, 2007, Issue 4.

[4] Article 11 of the Patent Law of the People's Republic of Law: " After the grant of a patent for an invention or utility model, except otherwise provided for in this Law, no entity or individual may, without the authorization of the patent right holder, exploit the patent, that is, to make, use, offer to sell, sell or import the patented product, or use the patented process, and use, offer to sell, sell or import the product directly obtained by the patented process, for production or business purposes."

[5] If we look back at the history of the "Bolar Exception", it is clear that that it came into being through legislation rather than judicial decisions. In the Rocke v. Bolar case, it was Bolar, a generic drug manufacturer,

who lost the case. And it was after the case that the Hatch-Waxman Act and the Bolar Exception thereof was introduced.

[6] See WT/DS114/R, Canada-Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel

[7] R represents 2-amino-5-guanidinovaleric acid; G amino acetic acid; and D asparagic acid.

[8] If the patentee could not, before the final judgment is reached, secure an injunction against the defendant to prevent the latter from conducting the clinical test and applying for the market approval ,the stay of the case is in fact a measure to recognize the defendant's freedom in using the said patent that way. Even if an interpretation rendered by the said competent is not retroactive following the procedure suggested in this article, the defendant could, at worst, only be held liable for damages under Article 64 of the Patent Law.

[9] Klinische Versuche II, Federal Supreme Court, April 17, 1997, RPC 1998, 424

[10] For understanding of Experimental Exemption in European, one could see "Harmonization due for pre-expiry trials in Europe" at: http://www.managingip.com/Article.aspx?ArticleID=1321533.

[11] Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis, Murray F. and Stern S., 2004.

[12] See Gower's Review of Intellectual Property, Pp.45-46.

[13] See the Draft Amendment to the Patent Law of the People's Republic of China (the Draft Amendment for public opinion), Pp.28-29, at http://www.sipo.gov.cn/sipo/tz/gz/200608/t20060808_106811.htm

[14] See Ibid, Appendix 2: Statement Regarding the Draft Amendment to the Patent Law of the People's Republic of China (the Draft Amendment for public opinion), P.74