Compelled Choice Made in Dilemma:

Comments on the Issue of Application of Law in the First Case of "Bolar Exception" in China

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I. Introduction

On 20 December 2006, the Beijing No. 2 Intermediate People's Court (the Court for short) rendered its first-instance judgement on the Japanese Sankyo Co., Ltd.) (Sankyo for short) v. the Beijing Wansheng Drug Co., Ltd. (Wansheng for short), a case of infringement of the patent for the pharmaceutical "Olmesartan medoxomil", establishing that Wansheng's acts of making the pharmaceutical with Sankyo's patented process and using it in its clinical trial and the application for regulatory registration to acquire these pharmaceutics did not constitute patent infringement.[1]

The interested parties did not appeal and the ruling has taken effect. The case, selected as one of the 10 major IP-related cases in Beijing in 2006, is the first case of "Bolar exception"[2] in which infringement is not established. People

於臨床實驗行爲。在這種兩難困境中,爲了避免上文所述的司法標準前後相悖的問題,適用《專利法》第 11 條,從不具有生產經營目的的角度,把臨床實驗行爲排除在侵權行爲的範疇之外,就成爲了一種多少有些無可奈何的變通選擇。

但正如前文所述,該案在適用法律上的這種變通選擇仍然難逃法理質疑,也與國際慣例不符,同時也避免不了司法審判標準的前後相互矛盾,因爲從法理角度分析,如果能夠把臨床實驗行爲定性爲"不以生產經營爲目的",從而將其排除在《專利法》第 11 條所禁止的行爲範疇之外,那麼今後依據第 11 條來處理"Bolar 例外"情形就可以了,何必再在《專利法》的侵權豁免規則體系中爲其另立專門條款呢?相反,《專利法修訂草案》專門確立"Bolar 例外"侵權豁免條款,這種做法本身就已證明,該條款所豁免的行爲恰恰是屬於《專利法》第 11 條所禁止的行爲,否則何來豁免的必要呢?

因此,筆者個人認爲,在當前的國內形勢下,中國要在醫藥專利保護制度中引入"Bolar 例外"原則,應當借鑒日本、德國和 2000 年以後的法國在相關判例中的做法和經驗,即通過對《專利法》中原有的科學研究實驗例外原則進行適度的擴大解釋,使其涵蓋"Bolar 例外"情形,這樣就可以及時解決中國當前所面臨的在"Bolar 例外"問題上立法與實踐嚴重脫節的問題,既可以使司法部門在這類案件的審判實踐中,免於陷入要麼遵循法理按侵權論處但卻違背國際潮流,要麼遵循國際潮流給予侵權豁免但卻背離法理的兩難境地,更能使中國目前仍然以仿製爲主的相對落後的醫藥產業能夠早日享受到其國際同行早已享有的合法權益,使廣大公衆也能夠在醫藥專利期滿後早日享受到價格低廉但療效不變的仿製產品。■

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[1] 參見北京市第二中級人民法院(2006)二中民初字第 04134 號民事判決書。

[2] "Bolar 例外"原則是一項專門適用於藥品和醫療器械等相關領域的專利侵權豁免原則。實踐中,也有人稱之爲"臨床實驗例外"原則或"Bolar 條款"。該原則的基本涵義是指,爲了對藥品和醫療器械進行臨床實驗和申報註冊的目的而實施相關專利的行爲,不視爲侵犯專利權,給予侵權豁免。有關"Bolar 例外"原則的詳細情況,可參見筆者所著"'Bolar 例外'原則的創立、發展及其在中國的應用"一文(http://www.li-fang.com.cn)。

[3] 參見吳玉和:"專利藥品的新藥臨床實驗不構成專利侵權?",載《中國專利與商標》2007 年第 2 期。

[4] 參見北京市第二中級人民法院(2005)二中民初字第 6026 號民事判決書。

from the community hold that this "ruling has presented the latest judicial view on this long controversial issue."[3] However, the grounds on which the Wansheng's acts were not established an infringement are different from the common international practice relating to the application of the "Bolar exception" doctrine. As a result, the judgement of the case has given rise to some debate.

According to the standard established in the judgement, the Beijing No. 2 Intermediate People's Court decided, on 20 June 2007, on non-infringement in case the US Eli Lilly and Company and Ganli Pharmaceutical Inc., also a case of "Bolar exception" involving the pharmaceutical of "biphasic recombinant insulin lispro injection 75/25".[4]

II. The case in brief

The plaintiff Sankyo filed, on 21 February 1992, an application with the Chinese Patent Office for a patent for the invention of a process for preparing pharmaceutical recombinant for treating and preventing high-blood pressure symptoms, and was granted the patent ZL 97126347.7 (the patent in suit) on 24 September 2003. In 2005, the plaintiff discovered that the defendant Wansheng was applying to the China State Drug and Food Administration (SDFA) for registration of a new drug "Olmesartan medoxomil" for marketing the drug soon. The plaintiff argued that the Olmesartan medoxomil, of which the defendant applied for registration, was made with the patented process involved. Besides, it had made the Olmesartan medoxomil under the Drug Registration and Administration Measures in the phase of clinical trial and application for marketing it. Therefore, it, together with the Shanghai Sankyo Pharmaceutical Co., Ltd. (Shanghai Sankyo), an entity exploiting its patent in China, sued Wansheng on 16 February 2006 in the Beijing No. 2 Intermediate People's Court of infringing its patent right for the process invention in making the pharmaceutical in suit.

In said case, Wansheng did not obtain the regulatory documents for making said product when the suit was instituted; hence the plaintiff's accusation was all directed to Wansheng's acts to make and use the pharmaceutical in suit in an attempt to obtain the necessary registration information in the course of clinical trial and application for marketing said pharmaceutical. This is a typical case of the "Bolar exception".

During the court trial, Wansheng defended that it had made Olmesartan medoxomil only to get and present the information necessary for the administrative approval of said pharmaceutical, and to send the information to the state drug administration with a view to obtaining the new drug certificate and production approval. It had been concluded in the relevant US laws and the Japanese judicial practice that acts of the nature did not constitute infringement of the patent right. This was also true in the relevant Chinese judicial interpretations being made and the draft Amendment to the Patent Law. Therefore, Wansheng's act did not infringe the patent right in suit, and it petitioned the court to reject the plaintiff's litigant claims.

On 20 December 2006, the Beijing No.2 Intermediate People's Court made its first-instance judgement, in which it was pointed out that the process used by Wansheng was substantially identical with the patented process in suit. According to the evidence presented, however, the accused Olmesartan medoxomil was still in the phase of pharmaceutical registration examination. While the defendant Wansheng had used the patented process and made the pharmaceutical for the purpose of clinical trial and application for production approval, its act of making it was to meet the need for the administrative examination and registration of the pharmaceutical by the related State administrative authority to test the safety and effectiveness of the pharmaceutical in suit it had made. Given that the defendant did not make the pharmaceutical in suit directly for the purpose of selling it, so it was not an act of exploitation of the patent for the purposes of production and business under the Chinese Patent Law. Accordingly, this court held that Wansheng's act did not infringe the patent right in suit.

III. Compelled choice made in dilenma: analysis of application of law in the above-mentioned case of "Bolar exception"

In the above-mentioned "Bolar exception" case, it was decided that the defendant's act did not constitute an infringement of the patent right in suit on the grounds that the defendant did not make the pharmaceutical directly for the purpose of selling it, so it was not an act of exploitation of the patent for the purposes of production and business under the Chinese Patent Law, which shows that the decision has actually been made on the basis of Article 11 of the Chinese Patent Law.

This writer believes that it stands to reason or principle

that non-infringement conclusion should be made in the present case, and fully supports such a judgement. Against the backdrop of the established "Bolar exception" principle in the U.S., Japan and Europe to exempt such acts from the liability for infringement, China does not need to, nor should, raise the level of protection for pharmaceutical patent high above these countries and region do, otherwise, it would not be compatible with the practical situation in China, and, as well, go against the fundamental policy of due protection of the intellectual property right in China. For this reason, while the Chinese Patent Law does not directly, expressly spell out the provisions to base the exemption on, the relevant practice urges the People's Court to learn from the successful experience of foreign countries where similar cases have arisen to creatively apply the law, so as to ensure that domestic pharmaceutical enterprises can equally enjoy the fundamental rights and interests the pharmaceutical businesses in the developed countries have long been enjoying. The people's courts should not mechanically prohibit the domestic pharmaceutical enterprises from acting duly on the ground of "absence of express law provision for exemption". In this sense, the above case has taken the first significant, pioneering step forward in the application of law in this direction.

Nonetheless, in the aspect of selecting the specific law provisions to base the judgement on, this writer believes that it would be easier to use the international experience as the frame of reference and render the judgement more convincing and less controversial if Article 63 of the Patent Law that use of a patent only for scientific research and experiment is not deemed to be an infringement was applied as the law basis, rather than applying Article 11 of the Patent Law.

The provision of Article 11 of the Patent Law has only defined "for the production or business purposes" without further defining or distinguishing the direct or indirect nature of these purposes. In the present case, the defendant's act of making the pharmaceutical in suit for use in clinical trial and for obtaining the relevant registration information was performed entirely to apply for the required regulatory document to legitimately make and deal in the pharmaceutical in suit. Accordingly, its act is, at least, one "indirectly", if not "directly", for the production or business purposes. It is too far fetched, in the legal theory, to preclude such acts from what are prohibited under Article 11 of the Patent Law. In almost all the relevant cases of the "Bolar exception" in the U. S., Japan and Europe, acts of using patent to obtain the relevant registration information are adjudged to have been done for business purposes. Quite the opposite, it has been made clear in these cases that these acts of clinical trial for applying for permit for marketing the related products are purely for business purposes; hence the conventional doctrine of the test or experiment exemption from infringement is not applicable. The establishment of the first case of "Bolar exception" in China as one not for the production or business purposes and not an infringement under Article 11 of the Patent Law, which is a practice contrary to the internationally prevalent views, is by no means the best way to handle the case. In fact, although the plaintiff did not appeal after the first-instance judgement was made, to this writer's knowledge, it also considered the established nature of the case and application of law thereto were undue.

By contrast, it would be a better choice to judge the case by applying the exception doctrine of scientific research and experiment under Article 63 of the Patent Law as the law basis. This would render the judgement theoretically more readily acceptable and harmonious with the international practice. Internationally, in the absence of express provisions on the "Bolar exception" in the national laws in the legal community in Japan and Germany, and in France after 2000, the experiment exception doctrine under the respective patent law would be applied to cases like this, and these acts would not be established as infringement.

This writer conjectures that the Beijing No. 2 Intermediate People's Court applied Article 11, rather than 63, of the Patent Law probably because China follows the US and EU practice by setting forth a separate provision on the "Bolar exception" in its draft Amendment to the Patent Law that is now under the State Council for review.

It should be pointed out that where the judicial practice in China urgently requires the people's court creatively search for, from the existing system of law provisions on infringement exemption in the Patent Law, the basis that acts of clinical trial are not established as infringement, the legislative body is now, in the course of amending the Patent Law, unequivocally and separately setting the "Bolar exception" as a new infringement exemption standard independent of the doctrine of scientific research and experiment exception under the current Patent Law, the consequence of which is doubtlessly to make it impossible for the People's Court to extend the application of the experiment exception to the acts of clinical trial in the current judicial practice because it is obviously impossible for the People's Court to dis-

regard the provisions and explanations of the draft Amendment to the Patent Law and to treat the acts of clinical trial under the doctrine of scientific research and experiment exception; after the Amendment to the Patent Law is adopted and comes into force, acts of the kind are treated under the standards other than the doctrine, otherwise, the stability and certainty of the doctrine of scientific research and experiment exception in terms of its content and scope of application, and the seriousness of the judicial activity would be challenged.

The practical dilemma resulting from this legislative model may offer a proper explanation of the practice of the Beijing No. 2 Intermediate People's Court's application of Article 11, not Article 63, of the Patent Law to the above "Bolar exception" case as the law basis. As a matter of fact, during the trial of the case, the defendant kept drawing on the international experience and defending itself against the accusation of infringement under the provisions on scientific research and experiment exception, while the plaintiff referred to the legislative model of the "Bolar exception" provision in, and the explanation of, the draft Amendment to the Patent Law, arguing that the doctrine of scientific research and experiment exception was not applicable to acts of clinical trial. In this dilemma, to avoid above-mentioned contradictory judicial standards, it is somewhat a forced choice to apply Article 11 of the Patent Law and exclude acts of clinical trial from those of infringement for lack of the production and business purposes.

As discussed above, it is still very difficult for this accommodation in the law application in this case not to be jurisprudentially challenged, nor is it compatible with the international practice. The contradictory judicial standards are unavoidable because if it is jurisprudentially possible to establish the acts of clinical trial are not "for production or business pruposes", so as to preclude them from the acts prohibited under Article 11 of the Patent Law, then, cases of "Bolar exception" may be treated under said Article 11 in the future. Why is it necessary to set forth a separate provision within the system of rules on the infringement exemption of the Patent Law? Conversely, the practice of a special provision on the "Bolar exception" for infringement exemption in the draft Amendment to the Patent Law per se shows that acts to be exempted from liability for infringement are exactly those prohibited under the Article 11 of the Patent Law. If not so, why is this exemption necessary?

In conclusion, this writer believes that under the current situation in China, we should draw on the practice and experience from the relevant precedents of Japan, Germany and France after 2000 in their efforts to incorporate the "Bolar exception" doctrine into their respective system for the protection of patent for pharmaceuticals, that is, duly extended interpretation of the doctrine of the scientific research and experimentation exception to such an extent as to cover the circumstance of "Bolar exception", so that the matter of serious dissociation of the legislation from the practice in respect of the "Bolar exception" will be addressed in a timely manner in China. This will enable the judicial organ to stay away from the dilemma of imposing infringement liability by following the legal theory but going against the international trend or following the international trend and granting infringement exemption but going against the jurisprudential theory. Besides, this will make it possible for the relatively less advanced or mainly imitating, pharmaceutical industry in China to enjoy their legitimate rights and interests their foreign counterparts have long been enjoying, and make available to the public the imitated pharmaceutical products that are inexpensive and effective after the pharmaceutical patents expire. ■

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

[2] The "Bolar exception" doctrine is a doctrine of exemption from the liability for infringement of patents relating to pharmaceutical and medical appliances. In practice, it is also known as the "clinical trial exception" doctrine or the "Bolar provision". This doctrine substantially means that an act of exploiting a relevant patent for the purposes of clinical trial of a pharmaceutical or medical appliance and of application of registration is not deemed to be an infringement of said patent right and exempted from the liability for infringement. For the detail of the "Bolar exception" doctrine, see this writer's article entitled Creation, Development of "Bolar Exception" Doctrine and Its Application in China on (http: // www.li-fang.com.cn).

[3] See Wu Yuhe, Are Clinical Trials of Patented Pharmaceutical Exempted from Liability for Patent Infringement?, the China Patents & Trademarks, 2007, No.2.

[4] See the Beijing No. 2 Intermediate People's Court's Civil Judgement No. Erzhongminchuzi 6026/2005.