專利藥品的新藥臨床實驗不構成專利侵權?

2006 年 2 月，日本三共株式會社（專利權人）以北京萬生藥業有限責任公司在新藥註冊申請過程中使用了其專利方法，構成專利侵權行爲爲由，向法院起訴，要求被告停止侵權和賠償損失。2006 年 12 月，北京市第二中級人民法院一審認定：未經專利權人許可爲新藥註冊審批目的使用他人專利，不構成專利侵權。該判決爲這一長期有爭議的問題提供了最新的司法審判意見。

按照中國現行《專利法》的規定，未經許可爲生產經營目的實施他人專利的，構成專利侵權，而僅爲科學研究和實驗目的而實施他人專利的，不構成專利侵權。對這一規定，藥品仿製者和專利權人通常有兩種不同的解釋。藥品仿製者認爲，藥品的臨床實驗屬於科學研究和實驗範疇，其目的是向藥品審批機關提供新藥報批所需的有關藥品安全、有效的數據信息，不具有生產經營目的，因而不侵犯他人專利權；而專利權人則認爲，新藥臨床實驗固然一方面具有科學研究和實驗的性質，但另一方面其目的是爲了獲得藥品審批機關的新藥生產和銷售許可，具有生產經營目的，而不是僅爲科學研究和實驗目的，這種雙重目的的實施他人專利的行爲構成現行《專利法》意義上的專利侵權行爲。

早在 2000 年，在“葛蘭素”訴“西南合成”專利侵權案件中曾涉及同樣的問題。重慶中級人民法院審理此案，在一審判決中未就新藥臨床實驗是否構成專利

Are Clinical Trials Exempted from Liability for Patent Infringement?

In February 2006, the Japanese Sankyo Co., Ltd, (the patentee) brought an action in the court against the Beijing Wansheng Drug Industry Co., Ltd (the defendant) on the ground that the defendant had used its patented process in the course of application for registration of a new drug, requesting the defendant to cease its infringement and compensate for the damages. In December 2006, the Beijing No. 2 Intermediate People's Court ruled, upon hearing the case, that use of another person's patent for the purpose of regulatory approval of a new drug without the authorization of the patentee did not constitute an infringement. This ruling represents the latest judicial view on the issue of prolonged controversy.

Under the current Chinese Patent Law, unauthorized exploitation of another person's patent for the purpose of production and marketing constitutes an infringement of patent, but exploitation of another person's patent only for the purpose of scientific research and experimentation does not. Drug imitators and patentees usually had their own interpretation of this provision. For the former, clinical trial of a drug is an act of scientific research and experimentation for the purpose of presenting to the regulatory authorities the data and information about the safety and effectiveness of a drug required for the approval of the new drug, and not for the purpose of production and marketing, so it does not infringe another person's patent right. By contrast, for the latter, clinical trial of a drug, on the one hand, has the character of scientific research and experimentation, and, on the other, it is performed for the purpose of obtaining regulatory approval from the regulatory authorities for making and marketing a new drug, so it is performed for the purpose of production and marketing the drug, and not merely for the purpose of scientific research and experimentation. The act of exploiting another person's patent having these duel purposes constitutes an infringement of the patent right within the meaning of the current Patent Law.

As early as 2000, Glaxo v. Southwestern Pharmaceuticals, a case of patent infringement involved the same issue. The Chongqing Intermediate People's Court heard the case, and did not directly answer the question of

侵權作出正面回答，但全額支持了原告損害賠償的訴訟請求，而該損害賠償數額正是基於被告新藥臨床實驗期間爲新藥註冊目的使用專利而給原告造成的損失計算出來的。

2001 年，中國藥品監督管理局出台《新藥註冊管理辦法》，其中規定，在新藥註冊申請時，申請人需提供有關專利信息，並聲明其申請註冊的新藥及其生產工藝不侵犯他人專利。對他人已獲得專利權的藥品，申請人可以在藥品專利期屆滿前 2 年提出新藥註冊申請。

2003 年，最高人民法院起草了有關專利侵權判定的司法解釋，其中規定了有關新藥臨床實驗不構成專利侵權的條款。由於對草案內容存在爭議，該草案迄今未公佈實施。

2006 年，國家知識產權局在第三次專利法修改草案送審稿中，建議在《專利法》中增加免責條款：專爲獲得和提供藥品行政審批所需信息而實施他人專利的，不構成專利侵權。該草案尚在討論和研究之中。

在這種大的趨勢中，“三共”訴“萬生”案件的審判法官基於現行《專利法》的規定，作出了如下認定：“…涉案藥品尚處於藥品註冊審批階段，雖然被告萬生公司爲實現進行臨床試驗和申請生產許可的目的使用涉案專利方法製造了涉案藥品，但其製造行爲是爲了滿足國家相關部門對於藥品註冊行政審批的需要，以檢驗其生產的涉案藥品的安全性和有效性。鑒於被告萬生公司的製造涉案藥品的行爲並非直接以銷售爲目的，不屬於《中華人民共和國專利法》所規定的爲生產經營目的實施專利的行爲，故本案認定被告萬生公司的涉案行爲不構成對涉案專利權的侵犯。”■

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whether clinical trial of a new drug constituted an infringement of the patent in suit, but supported the plaintiff's full claim for the damages calculated on the basis of the economic losses caused because of the defendant's use of the patent for the purpose of regulatory approval of a new drug during the period of clinical trails.

In 2001, the China Drug Administration issued the Measures for the Registration and Administration of New Drugs, in which it is provided that when applying for the registration of a new drug, the applicant is required to provide the relevant patent information, and declare that the new drug it applies for registration and his process for making the drug does not infringe another person's patent. In respect of a drug for which another person has been granted the patent right, the applicant may file an application for the registration of a new drug within two years before the drug patent expires.

In 2003, the Supreme People's Court drafted the judicial interpretation with respect to patent infringement establishment, in which it is provided that clinical trial of a new drug does not constitute a patent infringement. The draft interpretation has not been officially issued to date as a result of the controversy on part of it.

In 2002, the State Intellectual Property Office proposed, in the Draft Third Amendment to the Patent Law (submitted to the State Council for review), addition of the provisions on exemption from liability: exploitation of another person's patent for the purpose of obtaining and providing the data required for the regulatory approval of a drug does not constitute a patent infringement. The Draft is now still under discussion and review.

In this general situation, the court of the present Sankyo case decides under the Patent Law that "... the drug in suit is under administrative examination and approval for registration. Although the defendant has used the patented process in suit to make said drug for the purposes of clinical trial for applying for approval of the production of it, its act of making the drug has been done to meet the requirement of the relevant State agency for the regulatory approval of the drug to test the safety and effectiveness of the drug it makes. Given that the defendant does not make the drug in suit directly for the purpose of marketing it, its act is not one to exploit the patent for the purposes of production and marketing under the Patent Law of the People's Republic of China. Accordingly, it is decided that the defendant's act does not constitute an infringement of the patent right in suit.■

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