

patent, and the SPC does not give its specific directives on the issue of judgement of indirect infringement of patent, it is rather difficult for these courts following the statutory laws to observe the specific provisions in imposition of civil liability on indirect/contributory infringement of patent. This may explain why cases of indirect infringement of patent are under jurisdiction of a few courts despite the fact that more than 50 Intermediate People's Courts and over 30 Higher People's Courts in China have the jurisdiction over case of patent infringement. ■

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¹ See Shanghai No. 1 Intermediate People's Court Intellectual Property Judgement No. Fuyizhongminwu (zhi)chudizi 212/2003.

² For the article on the issue of infringement of the patent right for "magnetic-mirror direct current electric arc furnace, visit <http://www.cn-falv.com/a/anli38/9426.html>.

³ See Jiangsu Higher People's Court's Civil Judgement No. Sumin-sanzhongzi 014/2005.

⁴ See Nanjing Intermediate People's Court's Civil Judgement No. Ning-minsanchuzi 245/2003.

⁵ See Shanghai No. 2 Intermediate People's Court Civil Judgement No. Fuerzhongminwu (zhi)chudizi 156/2005.

⁶ See the SPC Gazette, 1999, No.1.

Chinese Judges Reaffirm Experimental Use Exemption of Clinical Trials from Patent Infringement

Recently, the Beijing No. 2 Intermediate People's Court has published its Civil Judgements Nos. Erzhongminchuzi 13419-13423/2007, in which it is decided that use of another party's patent without license by the patentee for the purpose of regulatory registration of a new drug does not constitute an infringement of said patent. This decision represents a reaffirmation of the court's view presented in Pp58-59 Sankyo Co., Ltd. v. Wansheng (See the China Patents & Trademarks, 2007, No.2).

The Eli Lilly and Company was the plaintiff of the above five cases, and Beijing Ganli Drug Co., Ltd. is the defendant. The plaintiff exercised its patent rights in the five processes for preparing insulin-analog and for the preparation in these cases, arguing that the defendant's acts to apply to the State Food and Drug Administration (SFDA) for approval of the clinic trial of a "recombinant lispro insulin" and "biphasic recombinant lispro insulin injection 75/25" and of making recombinant lispro insulin injection and advertise on the internet its drug by the name "Suxiulin" (with the active element of lispro insulin) constituted an imminent infringement of its patent rights and an act of offering the drug for sale. The defendant argued that its accused acts were not acts

of exploiting another party's patent as mentioned in the Patent Law, and it acted for the purpose of administrative examination and approval of the drug. According to the common practice, use of another party's patent for the purpose of administrative examination and approval of the drug was not deemed to be an infringement or imminent infringement.

The court made it clear in the Judgements that the law protected the patent right and the plaintiff's invention patents should be protected under the Chinese Patent Law. However, the court did not substantively judge on whether the accused substance fell within the scope of protection of the patent rights, nor conduct a technical appraisal to ascertain whether the accused technology was identical with or similar to the patented technologies. Its judgement mainly based on the determination of the character of the acts of carrying on the clinic trial and making the drugs during the regulatory examination and approval of a new drug.

The court believed that according to the available evidence, the "recombinant lispro insulin" and "biphasic recombinant lispro insulin injection 75/25" for which the patentee accused the defendant of the infringement were still in the phase of administrative examination and approval for the registration of drug, and were not ready to market. While the defendant performed the acts of carrying on the clinic trial and applying for the approval for production, it did so to meet the needs for the administrative examination and approval of the drug by the

relevant State authorities to test the safety and effectiveness of the drugs in suit it made. Although the defendant was granted the regulatory approval for the drug "recombinant lispro insulin injection", and said drug was ready to market, the plaintiff failed to adduce evidence to prove that the defendant had made and marketed said drug. Accordingly, the defendant's act of making the drug in suit was not directly for the purpose of marketing it, so it was not an act of exploiting another party's patent for business purposes as mentioned in the Patent Law.

As regards the defendant's advertisement of the drug "Suxiulin" on the internet, the court held that it should not be determined that it had used any product obtained directly with the patented processes of the plaintiff in the drug it advertised. Besides, the available evidence did not show that the defendant had actually made and marketed the drug. Accordingly, the plaintiff's claims that the defendant's acts constituted an imminent infringement or an act of offering for sale were not supported by the court for lack of sufficient evidence.

Now an interested party has appealed to the Beijing Higher People's Court, and the Judgements are yet to take effect. Anyway, the judicial view presented in these Judgements will have a far-reaching impact on the clinic trial, examination and approval of new drugs in China. ■

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