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BEIJING HIGH COURT UPHOLDS VIAGRA PATENT IN CHINA

On September 7, 2007, the Beijing High People's Court rendered a decision in favor of Pfizer in a dispute about the validity of Pfizer's Chinese patent covering sildenafil citrate, more familiarly known as Viagra. This verdict rejects an appeal by a group of Chinese generic-drug companies and maintains the June 2, 2006, ruling of the Beijing No. 1 Intermediate People's Court, which overturned the July 5, 2004, decision of the Patent Reexamination Board ("PRB") invalidating Pfizer's Viagra patent in China. With no further appeal available, this decision has closed a chapter in a patent dispute started in China six years ago. What has happened in this case presents a colorful illustration of the short but eventful history of patent protection of pharmaceuticals in China.

NO PATENT PROTECTION FOR PHARMACEUTICAL COMPOSITIONS IN CHINA PRIOR TO 1993

Viagra first became a patent subject when Pfizer filed U.K. patent application No. GB 9013750 on June 20, 1990. On the basis of this filing, Pfizer obtained patents in the U.S., Europe, Japan, and many other countries to protect sildenafil, its salts, other related compounds, and their use for treating angina, hypertension, heart failure, and atherosclerosis. Although China's patent law was enacted in 1984, it did not protect pharmaceutical compositions prior to 1993. Pfizer did not file any application in China based on the 1990 U.K. patent application.

PATENT PROTECTION FOR VIAGRA BECAME POSSIBLE IN CHINA IN 1993

In 1993, China joined the Patent Cooperation Treaty ("PCT") and amended its patent law to protect pharmaceutical inventions. On June 9, 1993, Pfizer filed U.K. patent application No. GB 9311920.4 to protect the use of sildenafil and other compounds for treating male erectile dysfunction. This patent application entered China through the PCT. On September 19, 2001, Pfizer obtained Chinese patent ZL94192386.X with a single claim:

> The use of 5-[2-ethoxy-5- (4-methyl-1-piperazinylsulphonyl)-phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d] pyrimidin-7-one or of a pharmaceutically acceptable salt thereof, or of a pharmaceutical composition containing any of the same, for manufacture of a medicament for curative or prophylactic treatment of erectile dysfunction in a male animal, including man.

The only compound named in the claim is sildenafil. No divisional application was known to have been filed by Pfizer to pursue additional claims.

THE VIAGRA PATENT UNDER ATTACK IN EUROPE

European patent EP 0 702 555, based on the 1993 U.K. application, was granted to Pfizer on March 11, 1998. This European patent has 11 claims: claims 1 to 9 cover the use of sildenafil and related compounds for treating or preventing erectile dysfunction, while claims 10 and 11 relate to the mechanism of action of these compounds:

10. The use of a cGMP PDE inhibitor, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic oral treatment of erectile dysfunction in man.

11. The use according to claim 10 wherein the inhibitor is a cGMP PDEv inhibitor.

Thirteen parties filed oppositions to the European '555 patent in December 1998. A revocation petition was also filed in the U.K. in February 1999. Thereafter, all claims of U.K. designation were revoked in November 2000 for lack of inventive step, and all claims of the European '555 patent were ruled invalid for lack of inventive step. Claims 10 and 11 of the European patent were also ruled invalid for lack of support for "oral" treatment.

THE PATENT INVALIDATION PETITION AGAINST THE VIAGRA PATENT IN CHINA

China's patent law does not include patent opposition or revocation proceedings; invalidation is the only means of challenging patent validity. An invalidation petition can be filed any time during the term of a Chinese patent by any individual or company that has reason to believe the patent is invalid in part or in whole. There is no standing requirement or requirement of timely filing. The patentee has opportunities to rebut invalidation arguments.

The Patent Reexamination Board of the State Intellectual Property Office ("SIPO") has exclusive jurisdiction in hearing and deciding invalidation petitions. The losing party has the right to appeal to the Beijing No. 1 Intermediate People's Court by filing an administrative lawsuit against the PRB.

On September 19, 2001, the day Pfizer was granted its Viagra patent in China, a Beijing resident by the name of Huaping Pan filed an invalidation petition against the patent. Thereafter, 12 Chinese companies also filed invalidation petitions against the patent. These 13 petitions were consolidated by the PRB for review. The petitioners used many of the arguments presented in Europe and came up with new arguments as well.

On July 5, 2004, the PRB made public its decision declaring the Viagra patent invalid on the ground of insufficient disclosure, while declining to rule on two other arguments presented by the petitioners, namely, the claim's lack of support from the specification and lack of inventive step.

On September 28, 2004, Pfizer filed an administrative lawsuit before the Beijing No. 1 Intermediate People's Court to appeal the PRB's invalidation decision. This lawsuit

effectively prevented Chinese generic-drug companies from obtaining marketing approval to sell their competing products because a Chinese patent is treated as valid until the invalidation decision has become final and nonappealable, and the State Food and Drug Administration ("SFDA") of China will not grant marketing approval to generic drugs while a valid patent exists for the original product.

Pfizer won the first-instance lawsuit on June 2, 2006, when the court ruled that the facts had been wrongly determined and the law erroneously applied in the PRB's invalidation decision. The court remanded the case to the PRB for further examination of the invalidation arguments that had not been addressed by the PRB.

This case was then appealed to the Beijing High People's Court by 10 of the 13 petitioners. The September 7, 2007, decision of the Beijing High People's Court is the final ruling regarding the invalidation ground of insufficient disclosure.

Unless the petitioners withdraw their invalidation requests, the PRB now has the task of deciding whether Pfizer's claim lacks support from the specification and lacks inventive step. Any such decision by the PRB is again subject to appeal and thus triggers another round of court proceedings.

LESSONS LEARNED ABOUT PATENT PROTECTION OF PHARMACEUTICALS IN CHINA

From its genesis in 1984, patent protection in China has evolved by leaps and bounds as China's economy has become integrated with the rest of the world. Recent statistics show that China has the world's third-busiest patent office (after Japan and the United States) in annual patent filings. More significantly, more patent infringement lawsuits were filed in China than in the United States in 2005 and 2006, and most of these lawsuits were between Chinese parties. This phenomenon has emerged despite a lack of formal discovery and the low level of damages granted by Chinese courts.

The Viagra patent story shows that a patent can be as effective in China as elsewhere in rewarding innovation and blocking generic competition. It is imperative that innovative pharmaceutical companies, such as Pfizer, take proactive steps in China to improve the quality of patent prosecution, gain sophistication with patent invalidation, and enforce patents against infringers. Enforcement of intellectual property rights in China will improve more visibly when more parties exercise their legal rights in the courts.

In the meantime, the world awaits the PRB's decision on the remaining invalidation arguments involving Viagra. ⏭