Experimental Use Exemption of Patent Infringement – A Brief Comparison of China and the United States

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Generally, the purpose of a patent is to award the patentee a limited market monopoly for disclosing his invention to the public. Experimental use of a patented invention, at least under certain circumstances, should not constitute patent infringement if such a use does not encroach upon the protected market. In many countries, including China and United States, experimental use of a patented invention is exempted, though varying in degree, from patent infringement. Here, we provide a brief comparison of the scope of experimental use exemption in the United States and China.

The United States

Historical Development

Historically, United States provides a narrow exemption from patent infringement liability for experimental use. The rationale behind the exemption was that "a man who constructed such a machine merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects" should not be punished.[1] This historical trend took a turn in 1984, starting from the case of *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc*.[2]

In that case, Bolar conducted bioequivalence studies, seeking FDA approval to market generic flurazepam, before Roche's flurazepam patent expired.[3] Roche sued Bolar for patent infringement.[4] The trial court (U.S. District Court for the Eastern District of New York) ruled in favor of Bolar, holding no liability under the common law experimental use exemption doctrine.[5] On appeal, the U.S. Court of Appeals for the Federal Circuit reversed, holding that the "experimental use" exception is narrow, and does not apply to tests having a commercial objective.[6]

Soon after the *Bolar* case, the U.S. Congress enacted the Hatch-Waxman Act as part of the Drug Price Competition and Patent Term Restoration Act of 1984, which seeks to strike a balance between two competing interests, encouraging pioneer research and development on one hand, and enabling competitors to market low-cost generic copies of drugs on the other.[7] In particular, the Hatch-Waxman

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[1] *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).
[2] *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)
[3] *Id.* at 860.
[4] *Id.*
[5] *Id.* at 861.
[6] *Id.* at 863.
[7] Pub.L. No. 98-417, 98 Stat. 1585 (1984) (38 U.S.C. Section 271(e)(1)-(2) (2000)).

Act overrules Federal Circuit's decision in *Roche v. Bolar*, providing generic drug makers a "safe harbor" from patent infringement for testing "reasonably related" to obtaining FDA approval of an Abbreviated New Drug Application ("ANDA"). 35 U.S.C. § 271(e)(1). Thus, under the Hatch-Waxman Act, bioequivalence studies conducted in connection with ANDA submissions no longer constitute acts of infringement. This is the so-called "Bolar Exemption." In exchange, the mere paper submission of an ANDA for a drug claimed by an unexpired patent is automatically an act of infringement, even though the generic drug maker does not yet have an approved version of the drug entering the market. 35 U.S.C. § 271(e)(2).

In areas other than pharmaceutical testing for regulatory purposes, it appears that the common law experimental use exemption remains narrow: exemption applies only when the use of a patented invention is for pure scientific curiosity.[8] In *Madey v. Duke University*, Madey sued Duke University for patent infringement and Duke University raised the experimental use defense.[9] The Federal Circuit rejected Duke University's arguments, holding that the "experimental use" defense is "very narrow" and is limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[10] The court found that research conducted at universities not only furthers the university's "legitimate business objectives, including educating and enlightening students and faculty participating in these projects;" but "also serve, for example, to increase the status of the institution and lure lucrative grants, students and faculty."[11] Such research at a university therefore is not exempted from patent infringement liability.

Experimental Use Exemption in Pharmaceutical Context (the Bolar Exemption)

Since most of the disputes in the United States relating to experimental use exemption occur under the Hatch-Waxman framework, we discuss below the scope of the statutory exemption as construed by the court. The U.S. Supreme Court has construed section 271(e)(1) broadly to encompass any use reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs or veterinary biological products.[12] For example, the "safe harbor" applies not only to drugs, literally covered by the statutory test, but also to medical devices, not expressly spelled out in the statute. [13] The Supreme Court further reinforced that "[the experimental use] exemption from infringement extends to all uses of patented inventions that are reasonably related to

[8] *Madey v. Duke University*, 307 F. 3d 1351, 1362 (Fed. Cir. 2002).
[9] *Id.* at 1352.
[10] *Id.* quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).
[11] *Madey*, 307 F.3d at 1362.
[12] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 663, 110 S.Ct. 2683, 2685 (1990)
[13] *Id.*

the development and submission of any information under the FDCA [Federal Food, Drug, and Cosmetic Act]," including preclinical testing and testing data not ultimately included in the drug application.[14]

Under the guidance of the U.S. Supreme Court, both the Federal Circuit and various federal district courts have taken quite liberal interpretations of section 271 (e)(1). For example, the Federal Circuit held that the statute does not look to the underlying purposes or intended consequences of a use, so long as the use is reasonably related to the FDA approval.[15] One federal district court held that if it was reasonable for a party to believe that there was a decent prospect that the "use" in question would contribute to the generation of information that was likely to be relevant in the FDA approval processes, it should not matter whether other reasonable persons might have concluded that FDA approval could be secured even without the information in question.[16] Even after receiving FDA approval, if post-approval studies are "materials the FDA demands in the regulatory process," those studies could still fall within the safe harbor provision.[17]

Nevertheless, courts have set forth limits on the application of section 271(e)(1). For instance, the Federal Circuit held that the safe harbor under section 271(e)(1) only applies to products that are subject to FDA approval.[18] If a product does not need approval from a regulatory body, the 271(e)(1) exemption does not apply.[19] Furthermore, studies recommended by a marketing department, not conducted for the purpose of regulatory approval, are not entitled to exemption.[20] In addition, a federal district court held that section 271(e)(1) offers no protection to a drug maker's use of a patented invention to develop its own patentable product.[21] The rationale was that the section 271(e)(1) safe harbor was designed to allow generic competitors to enter the market with a product that competes with a patented invention at precisely the time the patented invention loses its protected status.[22] A drug maker, who develops its own new drug product using a patented invention, cannot take advantage of this safe harbor.[23]

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[14] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193; 125 S.Ct. 2372; 162 L.Ed. 2d 160; 2005 U.S. LEXIS 4840. (2005)
[15] *AbTox, Inc. v. Exitron Corporation,* 122 F.3d 1019, 1020 (Fed. Cir. 1997). modified 131 F. 3d 1009 (Fed. Cir. 1997).
[16] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.,* 3 F. Supp. 2d 104, 106 (D. Mass. 1998)
[17] *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.,* 686 F.3d 1348, 1359-60 (Fed. Cir. 2012).
[18] *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008)
[19] *Id.*
[20] *Amgen, Inc. v. ITC*, 565 F.3d 846, 852 (Fed. Cir. 2009).
[21] PSN Ill., LLC v. Abbott Labs. & Abbott Bioresearch Ctr., Inc., 2011 U.S. Dist. LEXIS 108055(N.D. Ill. Sept. 20, 2011)
[22] PSN Ill., LLC v. Abbott Labs. & Abbott Bioresearch Ctr., Inc., 2011 U.S. Dist. LEXIS 108055(N.D. Ill. Sept. 20, 2011)
[23] *Id.*

China

Historical Development

Experimental use exemption was included in China's very first Patent Law in history, which was enacted in 1984. The Patent Law of 1984 in China states that use of a patent solely for the purposes of scientific research and experimentation shall not be deemed as an act of infringement. There have been relatively few judicial cases concerning experimental use exemption in China. Nevertheless, it was generally interpreted narrowly and was limited to scientific research and experimentations carried out specifically on the patented technology as such. The purpose of such exempted use is to give scientists and researchers freedom to characterize the technology, to look into the effect achieved by the technology, or to further improve the technology. [24] Under this interpretation, it may be difficult to consider clinical trials conducted by a generic company for regulatory purposes as being exempted from patent infringement. For instance, in *Glaxo v. Southwest Synthetic*, the court's decision was in favor of the patentee, holding that regulatory clinical trials by the generic company were not exempted from patent infringement. [25]

In 2003, the Chinese Supreme People's Court delivered a draft judicial interpretation (for public comments) entitled "Provisions Concerning Several Issues in the Trials of Cases of Dispute over Patent Infringement," which proposed that an act of using a patented invention for the purpose of clinical trials to satisfy regulatory requirements shall be considered to fall into the scope of experimental use exemption. That draft, however, never became legally effective.

The case *Sankyo Co., Ltd. v. Beijing Wansheng Drug Indus. Co., Ltd* brought a new round of attention to this issue in 2006. In that case, Wansheng used a patented process owned by Sankyo for regulatory purpose. The final judgment found no infringement by Wansheng. However, the decision did not rely upon experimental use exemption. The court did not consider Wansheng's act as being for "business purpose." The court reasoned that the use of Sankyo's patent by Wansheng was necessitated by relevant government regulations, which require clinical trials of the drug to satisfy the requirements for obtaining a license for production; the purpose of the trial was to test the safety and efficacy of the drug

[24] Explication to the Newly-Adapted Patent Law (in Chinese only), written by Legal Affairs Department of the SIPO, Intellectual Property Publishing House Co., Ltd., 2001, pages 366-368.

[25] *Glaxo v. Southwest Synthetic Pharm. Corp., Ltd.,* 1995 Chong-Jing-Chu-Zi-406 (Chongqing 1st Interm. People's Ct. 1995).

but "not directly for sale of it."[26] A similar opinion was delivered by the court in *Elli Lilly v. Gan & Lee Pharm*. in 2007. [27]

A provision, equivalent to the Bolar exemption in the U.S., was introduced for the first time in China's Patent Law when the Law was amended in 2008, which is currently in effect. Article 69 of the Chinese Patent Law recites "[t]he following shall not be deemed to be patent right infringement: . . . (4) [a]ny person uses the relevant patent specially for the purpose of scientific research and experimentation; and (5) [a]ny person produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any other person produces or imports patented drugs or patented medical apparatus and instruments especially for that person".[28] Notably, the Chinese Bolar exemption provision exists in parallel with the provision on general experimental use exemption.

Current Practice of Experimental Use Exemption

It does not seem that there are any precedential cases in China's judicial practice concerning experimental use exemption. As mentioned above, however, "experimental use" was generally considered as referring to scientific research and experimentations carried out specifically on the patented technology as such, but not those that are conducted by exploiting the patented technology as a means. This understanding is reflected in a directive delivered by Beijing Higher People's Court in 2013, entitled "Guidelines for Judgment of Patent Infringement[29]" ("the Guidelines for patent infringement"), although that directive is not generally binding and is aimed only at providing guidance to the trials of patent cases in various courts in Beijing. In addition, the provisions on experimental use exemption are applicable regardless of whether the use is for a business purpose.

Current Practice of Bolar Exemption

There have not been any concluded cases where the court makes a decision based on the Bolar exemption provided in the Chinese Patent Law. Nevertheless, the court decisions in *Sankyo Co., Ltd., v. Beijing Wansheng* and *Elli Lilly v. Gan & Lee Pharm.* could shed some lights in the application of the

[26] *Sankyo Co., Ltd.,v. Beijing Wansheng Drug Indus. Co.,* Ltd., 2006 Er-Zhong-Min-Chu-Zi-04134 (Beijing 2nd Interm. People's Ct. 2006).
[27] *Elli Lilly v. Gan & Lee Pharm.* 2007 Er-Zhong-Min-Chu-Zi-13419-23 (Beijing 2nd Interm. People's Ct. 2007).
[28] Art 69, Patent Law of the People's Republic of China (promulgated Dec 27, 2008, effective Oct 1, 2009), PRC President Order No.8 of 11th NPC. See http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html
[29] Art 123, Guideline for judgment of patent infringement. See http://www.chinacourt.org/article/detail/2014/01/id/1175142.shtml (in Chinese only)

Bolar exemption in China. As in those cases, the Bolar exemption in China could be applicable to drugs and medical devices that are made according to a patented process, as well as drugs and medical devices that are patented per se. In a regulative directive (on trial) enacted by the State Intellectual Property Office ("SIPO"), entitled "Guidelines for Determination of Patent Infringement and Passing Off," the Chinese Bolar exemption is interpreted as applicable not only to patents on drugs and medical devices as such, but also to those on an active ingredient of a drug, on a process for preparing a drug, on a process for preparing an active ingredient of a drug, on parts specifically for use in a medical device, and on a method of using a medical device. [30] This directive is binding on local Intellectual Property Offices, which are government administrative agencies handling patent infringement complaints filed with them.

Furthermore, the Chinese Patent Law does not include sale and offering for sale in the listed acts applicable under the Bolar exemption. Usually, drugs and medical devices cannot be put on market when the regulatory approval process is still ongoing. As to acts of offering for sale such as display on a trade fair, it is believed that such acts have nothing to do with obtaining information for regulatory purposes and should be excluded from the Bolar exemption.[31] In fact, these acts are indeed excluded from SIPO's directive noted above.

Another question that arises is whether foreign regulatory approval should be included in the Chinese Bolar exemption. The SIPO seems to believe that it is desirable to include both domestic and foreign regulatory approval in the Bolar exemption[32] and it has indeed done so in its directive entitled "Guidelines for Determination of Patent Infringement and Passing Off." However, some courts seem to interpret the Bolar exemption as applicable only domestically.[33]

Comparative Perspective

The experimental use exemption doctrines in the United States and China are conceptually similar, as both provide infringement exemptions in the experimental use context and in the context of pharmaceutical and medical device approval. However, it is to be noted that in China's codified patent law, experimental use exemption and Bolar exemption are separate, parallel provisions. In other words, Bolar exemption is not construed as being specific to experimental use exemption in the Chinese Patent Law. Perhaps the Chinese legislators were not able to categorize use of a patent for regulatory purpose

[30] *http://www.sipo.gov.cn/tz/gz/201309/t20130925_819909.html* (in Chinese only), see Part I, Chapter Three, Section 7.
[31] Yin Xintian. *Introduction to the Patent Law of China* (in Chinese only), 835 (Intellectual Property Publishing House Co., Ltd., 2011)
[32] *Supra*. at 836.
[33] Art. 124 of the Guidelines for patent infringement.

into experimental use since the former could hardly be considered as pure philosophical use. Indeed, an act of applying for regulatory approval would usually be for the purpose of doing business but have little to do with philosophy.

The doctrines are applied differently in the two countries in several important aspects. For example, the Chinese experimental exemption doctrine appears to focus on the inquiry of how a potential infringer uses a patented technology (experimentation on the patented invention per se or employing the patented invention as a means), rather than the purpose of the use (business or philosophical). The United States, however, focuses on the latter.

Also, the Bolar exemption under 35 U.S.C. § 271(e)(1) encompasses an act of offering to sell or selling a patented invention, while the relevant Chinese statute does not include such an act in the exemption list. Another important difference between the legal frames of the United States and China is China's lack of patent term extension for a patent that covers an approved drug and a proper patent linkage system that links patent enforcement activities with the drug approval process. Thus, the Chinese Bolar exemption is often dubbed as a "naked" Bolar exemption, which offers competitive advantages to the generic drug companies but omits a balancing remedy to innovative drug companies.

Nevertheless, the current Chinese Patent Law is viewed by the authority as commensurate with the current state of the domestic pharmaceutical industry where innovation lags behind its U.S. counterpart. That being said, the innovative pharmaceutical industry in China is growing very fast and may demand further amendment of the Chinese patent and drug registration laws to more properly balance the incentives for innovation and access to affordable medicine.

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