PharmAsia News

March 02, 2009

Insider Analysis From Morrison & Foerster LLP: China's Bolar Exemption - Beware of the Uncertainties of Its Reach And Scope (Part 1 of 2)

By Janet Xiao, Morrison & Foerster LLP, Palo Alto and Michael Vella, Morrison & Foerster LLP, Shanghai

The third amendment to China's Patent Law, approved by the National People's Congress Standing Committee in late 2008 and taking effect on Oct. 1 adds a new "Bolar" provision.

This provision exempts from patent infringement "the manufacture, import, or use of a patented drug or patented medical apparatus by any person in order to acquire information necessary for regulatory approval, or the manufacture or import of a patented drug or patented medical apparatus by any person solely for others to acquire information necessary for regulatory approval."

The addition of the Chinese Bolar provision is welcomed by the public as bringing China in line with other countries that already have adopted similar Bolar-type provisions, such as the United States, Europe and India. The provision also is lauded for making it easier to launch generic drugs right after the expiration of patent protection. The scope and impact of the Chinese Bolar provision, however, remain to be determined.

To appreciate the uncertainties that remain after the enactment of the Chinese Bolar provision, it is useful to recall the development of the law applying the U.S. and European Bolar provisions. In both cases, the enactment of the Bolar provision left many unresolved issues that needed to be addressed by the courts. As discussed below, we can expect that the Chinese courts will be similarly occupied in determining the exact reach and scope of this important exception to patent infringement.

***Roche v. Bolar*: Origin of the Bolar Exemption**

The "Bolar" exemption got its name from a U.S. case, *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*,[i] which involved a dispute between pharmaceutical giant Roche and Bolar Pharmaceutical Co., a manufacturer of generic drugs. During the last six months of the term of Roche's patent, Bolar began to perform bioequivalency and biostability tests on Roche's patented drug. In response, Roche sued Bolar to enjoin Bolar from using its patented drug. The Eastern District Court of New York found that Bolar's use of the patented drug was *de minimus* and experimental, and thus not an infringement of Roche's patent.[ii]

The Federal Circuit reversed the decision. The court noted that two significant distortions in patent law existed as a result of the U.S. FDA drug approval process. First, the delay in FDA approval significantly shortened the length of the effective term of a patent. Second, innovative drug developers enjoyed a longer period of monopoly by preventing generic drug developer from using the patented drug for testing purposes until after the patent expired.[iii] Nevertheless, the court stated that Congress would be the proper forum to address these issues and held that, under the law as it then existed, Bolar's use of Roche's patented drug for testing purposes constituted patent infringement.[iv]

U.S. Safe Harbor Provision

Following the *Roche* decision, both innovative and generic drug developers appealed to Congress for a remedy for the two distortions resulting from the FDA approval process. Innovative drug developers lobbied for extended patent terms in order to compensate for the time they spent on the FDA approval process.

Generic drug developers, on the other hand, argued that they should gain access to the FDA approval process before the pioneer drug patents expire so that generic products could be brought to the market immediately after expiration of the patents. In response to these lobbying efforts, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, popularly known as the Hatch-Waxman Act, in an attempt to create a compromise between the conflicting interests of pioneer drug developers and generic drug developers.

Title II of the Hatch-Waxman Act provides both a patent term extension provision and a safe harbor provision to the general prohibition against patent infringement. The patent term extension provision, encoded in 35 U.S.C. §156, allows an extension of the patent term based on delay in the FDA approval process. The safe harbor provision, encoded in 35 U.S.C. §271(e)(1),

allows development of generic drugs prior to the expiration of the patent. Through the enactment of the statutes, Congress hoped to correct the *de facto* reduction of patent term caused by the FDA approval process while at the same time allowing earlier entry of generic drug developers.

Despite the specific legislative intent, the language of the statute seems very broad. It states: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under the Federal law which regulates the manufacture, use, or sale of drugs …. "

Courts encountering §271(e)(1) issues have generally interpreted the statute broadly to encompass not only activities related to generic drug development, but also those related to the development of new drugs and medical devices.[v] A number of activities have been found to be "reasonably related" to development and submission of information to FDA, and thus exempt under the §271(e)(1) safe harbor. These include, for example, using patented medical devices for collecting data prior to submission of an FDA application,[vi] demonstrating patented devices at medical conferences,[vii] stockpiling products prior to FDA approval,[viii] and conducting post-approval studies to collect FDA-required follow-up data on the approved products.[ix]

In *Merck v. Integra*,[x] the U.S. Supreme Court further clarified that the §271(e)(1) safe harbor may encompass preclinical studies pertaining to the safety of drugs in humans and those related to a drug's efficacy, mechanism of action, pharmacology and pharmacokinetics.

The Court also stated that experimentation on drugs that are not ultimately the subject of an FDA submission, or use of patented compounds in experiments that are not ultimately submitted to FDA, may be exempt under §271(e)(1). The only requirement is that there is a reasonable basis to believe that the experiment will produce the type of information that is relevant to an FDA submission, and, if successful, would be appropriate to include in a submission to FDA.

Notably, §271(e)(1) on its face is not limited to a patented drug or medical device, but rather to a "patented invention." In *Proveris Scientific Corp. v. Innovasystems, Inc.*,[xi] the Federal Circuit addressed the question of whether the safe harbor can be read so broadly to encompass a patented research tool, namely, a product that is used in the development of FDA regulatory submissions but is not itself subject to the FDA premarket approval process.

Proveris involves a patented apparatus for characterizing aerosol spray in drug-delivery devices. Although the apparatus itself is not subject to FDA approval, it is used in connection with FDA regulatory submission of information about drug delivery devices. As part of its defense to a patent infringement allegation, Innovasystem invoked the safe harbor provision.

Affirming a decision by the lower court, the Federal Circuit held that the safe harbor provision does not immunize Innovasystem from patent infringement. The court reasoned that, because §271(e)(1) was enacted together with the patent term extension provision 35 U.S.C. §156 to eliminate two unintended distortions of the effective patent term resulting from the FDA premarket approval process, these two provisions were "meant generally to be complementary."

Thus, interpreting the phrase "patented invention" in the safe harbor provision to include all products listed in the patent term extension provision would produce "a perfect product fit" between the two provisions. Because Proveris' patented apparatus is not subject to an FDA approval process, and therefore does not face a reduction of the effective patent life, it is not eligible for the patent term extension, according to the court. At the same time, because Innovasystem's apparatus is not subject to FDA approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innovasystem does not need the safe harbor protection.

While *Proveris* left many questions unanswered, it indicates U.S courts' willingness and tendency to go back to the purpose and legislative intent of the statute for guidance when determining the scope of the safe harbor provision.

Janet (Jian) Xiao *is a senior associate specializing in patent law in the Palo Alto office of Morrison & Foerster LLP. She primarily represents clients in areas of biotechnology and pharmaceutical industry in their worldwide patent procurement, patent portfolio management and strategic planning. Dr. Xiao has significant experience in analyzing complex patent portfolios as well as mining and strengthening her clients' patent portfolio. Besides patent prosecution, her practice includes patent reexamination, patent litigation, preparation of freedom-to-operate opinions and due diligence.*

Michael Vella *is a Partner in the Litigation Department of Morrison & Foerster LLP and is the Head of the Litigation Practice in China. Mr. Vella assists clients in the litigation of international business disputes, including cases involving intellectual property, securities, antitrust, products liability and international arbitration. Mr. Vella also counsels clients in the electronics and biotechnology industries regarding litigation avoidance and adversarial license negotiations. Before relocating to the firm's Shanghai office, Mr. Vella was ranked as one of the top Intellectual Property Litigation Lawyers in Southern California by Super*

Lawyers.

[Editor's note: This is part one of a two-part feature. Look for part two in an upcoming issue of PharmAsia News.]

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[i] 733 F.2d 858 (Fed. Cir. 1984).

[ii] *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.,* 572 F. Supp. 255 (E.D.N.Y. 1983).

[iii] *Id.* at 863-865.

[iv] *Id.* at 865.

[v] *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661 (1990).

[vi] *AbTox, Inc. v. Extrion Corp.,* 122 F.3d 1019 (Fed. Cir. 1997).

[vii] *Teletronic Pacing Systems, Inc. v. Ventritex*, 982 F.2d 1520 (Fed. Cir. 1992).

[viii] *NeoRx Corp. v. Immunomedics, Inc*., 877 F. Supp. 202 (D. N. J. 1994).

[ix] *Classen Immunotherapeirs, Inc. v. King Pharmaceuticals, Inc.,* 466 F. Supp. 2d 621 (N.D. Md. 2006).

[x] *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193 (2005).

[xi] 536 F.3d 1256 (Fed. Cir. 2008).