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

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[Editor's note: This is part two of a two-part feature story. [Part one](#) appeared in *PharmAsia News*, March 2, 2009.]

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.

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.

Following the footsteps of the United States, the European Union introduced a similar provision in 2004, popularly referred to as the "European Bolar provision," in Directive 2004/27/EC. It states: "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3, and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medical products."^[1]

Directive 2004/27/EC also introduced an eight-year period of data protection plus a two-year period of marketing protection, which means that a generic drug cannot be placed on the market until 10 or more years have elapsed from the initial authorization of the innovative drug. The simultaneous introduction of the new data protection regime and the Bolar provision was seen as a compromise between the conflicting interests of innovative drug developers and generic drug developers.^[2]

EU member states have taken different approaches to the implementation of the European Bolar provision. The UK, for example, has narrowly interpreted the Bolar exemption to apply only to activities related to generic drug development. Germany, on the other hand, has extended the scope of the Bolar exemption to all types of applications for marketing authorization, including applications for approval of new drugs.^[3] Until the European Court of Justice is called on to bring clarity and consistency to the interpretation of the statute, the European countries will likely apply different standards when applying the European Bolar provision.

Uncertainty Of The Bolar Exemption in China

Prior to the enactment of the third amendment, the Chinese Patent Law had not clearly stipulated whether using patented technology for China State FDA approval constitutes patent infringement. However, in practice, Chinese courts had already established some Bolar exception cases. The first case was *Sangong & Shanghai Sangong Pharmaceutical, Ltd. v. Beijing Wansheng Pharmaceutical, Ltd.*,^[4] which was handled by the Beijing No. 2 Intermediate People's Court.

In that case, defendant Wansheng used the plaintiff's patented technology in an application for SFDA approval of a new drug. The court found that because Wansheng used the patented technology only to make the drug for the purpose of clinical trials and application for regulatory approval, Wansheng did not make the drug in dispute directly for the purpose of selling the product. Thus, the court held that such activities were not an infringement act of "exploitation of the patent for production or business purposes" under Article 11 of the Chinese patent law.

After the Sangong case, the Beijing No. 2 Intermediate People's Court issued five similar decisions involving similar fact patterns. Nevertheless, because China is not a common law country, later courts are not bound by these decisions. Furthermore, commentators have expressed concern that there is no legal basis for reading into Article 11 a distinction between direct and indirect exploitation for the purpose of production and business, and that such distinction could create undesired consequences if taken into other contexts.^[5]

With the introduction of the Bolar exemption in the third Amendment of Chinese Patent Law, there is now a clear legal basis for applying the Bolar-type exemption in China. However, the scope and reach of the Bolar exemption remains to be determined. For example, the provision does not explicitly exempt parties that “offer to sell” or “sell” patented drug or patented apparatus. This raises the question of whether an offer to sell a patented drug prior to the approval would be exempt under the Chinese Bolar provision.

Furthermore, it is unclear which activities would be considered as being conducted “in order to acquire information necessary for regulatory approval.” For example, would the Bolar provision exempt preclinical activities? Would post-approval activities be outside of the scope of the exemption? Would stockpiling products prior to SFDA approval be exempt?

Notably, unlike the U.S. safe harbor provision, the Chinese Bolar provision specifically calls out “patented drug” or “patented apparatus.” One can certainly argue that these terms are meant to encompass only the drugs and apparatuses that are the subject of the SFDA approval and thus do not encompass use of research tools. On the other hand, use of research tools could fall within the research and experimental-use exemption, which encompasses a broader range of activities than what the corresponding U.S. experimental use exception would allow.

Unlike the United States and Europe, China does not provide a complementary patent-term extension provision to counteract and balance the Bolar exemption provision. It is thus unclear whether and how the U.S. and European cases can be used as guidance in determining the scope and reach of the Chinese Bolar provision. Facing these uncertainties, parties using a patented technology to conduct FDA-related studies should not blindly rely on the Bolar exemption. Instead, they should be sensitive to the scope and limitations of the Chinese Bolar provision and conduct diligence before carrying out potentially infringing activities. Innovators, on the other hand, should be aware of the contours of the Bolar exemption and understand the limitations on their patent rights in view of the newly added Bolar provision in China.

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[1] Application of paragraphs 1, 2, 3, and 4 are application for generic drug approvals.

[2] Barnden, “EU Bolar Exemption is Not So Simple,” available on www.managingip.com/Article/2003422/EU-Bolar-exemption-is-not-so-simple.html.

[3] *Id.*

[4] Erzhongminchuzi, No. 04134 (2006).

[5] He, J. Intl. Prop. Law & Practice, 2008, Vol. 3, No. 8, pp. 490-491.

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