MILLER CANFIELD

China Allows Compulsory Licensing

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On May 1, 2012, China's newly released "Measures for Compulsory Licensing of Patent Implementation" (the New Measures) came into effect. By allowing China's State Intellectual Property Office (SIPO) to grant compulsory licenses for producing generic versions of branded drugs, the New Measures have the multinational big pharmas worried, especially as India just granted its first compulsory license for Bayer's anti-cancer drug Nexavar shortly before these New Measures took effect.

Are the New Measures Really New?

No compulsory license has ever been granted in China, but ideas and rules of compulsory licensing are not new in China. China's Patent Law of 2001 and its Implementing Rules already included provisions allowing compulsory licenses under certain circumstances, and such provisions were further clarified in China's Patent Law as amended in 2008. The New Measures integrate and replace two sets of older regulations: "Measures for Compulsory Licensing of Patent Implementation" (Order No. 31) promulgated in 2003, and "Measures for Compulsory Licensing of Patent Implementation Regarding Public Health" (Order No. 37) promulgated in 2005. Further, the New Measures provide more detailed and better defined procedures for examining and terminating compulsory licenses under applicable patent laws.

Under the New Measures, China's SIPO may issue and terminate compulsory licenses for invention patents and utility patents (not design patents) to a qualified entity or individual, considering three factors:

1. non-use of the patented invention or misuse of patent in violation of anti-monopoly law

2. public welfare, including "national emergency or extraordinary situation," "public interest," and "public interest" and

3. cross-license for exploitation of an improvement invention

If a compulsory license is granted, the parties may negotiate the royalties or ask the SIPO for adjudication on such fees. If a party is unsatisfied with the SIPO's decision on compulsory licensing, it can apply for an administrative review or initiate an administrative litigation.

Will China Be the Next India?

The broad and undefined descriptions of "national emergence or extraordinary situation" and "public interest" make multinational big pharma worried if and where China's SIPO will draw a line. Before the New Measures, China was similar to Japan which also had rules allowing compulsory licensing but never used them. Now, the New Measures raise the question whether such a situation will be changed. If China decides to follow the steps of India to actually grant a compulsory license (as did smaller countries such as Thailand, Indonesia, and Malaysia) to make expensive drugs less costly by granting compulsory licenses, many products may be affected. This raises special concerns for multinational pharmaceutical companies that have already contracted Chinese companies to make the key ingredients in their drugs as those Chinese companies may now be technically capable of making the products.

However, there are also strong reasons for China not to do so or do so lightly.

First, from a business perspective, granting a compulsory license by the SIPO will ring alarm bells for all foreign investors in China, including companies in other industries that compete based on innovation and technologies. This is contrary to China's long established policy to attract foreign investment, particularly high-tech investment.

Second, the current Five-Year Plan (2010-2015) released by the Chinese government emphasizes its goal to establish an innovation-oriented economy and to promote IP protections. It is difficult to imagine that without major policy and rule changes, the SIPO will suddenly act against China's national IP strategy and start to grant a compulsory license which is generally looked upon as discouraging innovation.

Third, granting a compulsory license almost certainly will attract objections from the governments of developed countries and spark international trade tensions. Therefore, it is very unlikely that China will take this step now or in the near future.

What Might Happen?

Despite the foregoing, one thing is sure. The New Measures are becoming a useful negotiating tool for the Chinese government. The clearest evidence is the current negotiation between the Chinese government and U.S.-based Gilead Science Inc. over Tenofovir – a drug for HIV treatment. China has been excluded from the Patent Pool for providing generic versions of Tenofovir to 111 countries. It seems that, after the New Measures took effect, Gilead offered certain concessions, e.g., by giving China a substantial donation of Tenofovir if China continues to buy an equivalent amount. Now, all eyes are on China to see how it will react with the New Measures, especially since China will lose its funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2013.

In addition, in spite of the low possibility for the SIPO to issue a compulsory license, the New Measures may still encourage more Chinese entities to file antitrust cases in courts, and look for evidence of patent non-use and raise public welfare arguments before the SIPO to support their case for a compulsory license. Thus, the multinational pharmaceutical companies would be better off to start preparing to fend off those applications.

Further, since a main argument for compulsory licensing is the high price of essential drugs, multinational pharmaceutical companies may need to consider local production of expensive imported drugs as a means to reduce the cost and the probabilities of SIPO to grant a compulsory license.

In summary, we believe that even with the New Measures, China is unlikely to change its patent practice or grant its first compulsory license right away. But the final result of the negotiation between the Chinese government and Gilead will shed some light on China's current attitude toward the uses of compulsory licensing.