CFDA Contemplates Chinese Version of Patent Linkage System [Rocky WU, JT&N, 2017-06-01]

On May 12, 2017, the China Food and Drug Administration (the "CFDA") issued Policies Concerning the Protection of the Rights and Interests of Innovators for Encouraging Innovation in Drugs and Medical Devices (draft for public comments, No. 55, 2017) (the "Policy No. 55"), which was issued for soliciting public comments until June 10. One of the key points of Policy No. 55 is that CFDA is planning to introduce the Chinese version of patent linkage system. The Policy No. 55 is a significant improvement over the experimented patent linkage system before under the 2007 China Drug Registration Regulations. The Policy No. 55 has really outlined the patent linkage system for the first time. Innovators can bring infringement actions prior to the CFDA's granting the marketing approval of the generic drug products in the first place. The CFDA can withhold the marketing approval of the generic drug products up to 24 months. Highlights of the Policy No. 55 are touched on below.

Available Patent Infringement Actions against Generic manufacturers

Under Article 1 of the Policy No. 55, there are the below two scenarios for the innovators to bring a patent infringement action against generic manufacturers before marketing approval of the generic drug products.

I. After the patent holder of the relevant drug patent receives notice from the applicant for generic drug products registration, the patent holder should bring a patent infringement action in the court within 20 days if the patent holder finds infringement of its patent. If the patent holder files the patent infringement action, they should notify the drug review institution.

II. If the patent holder of the relevant drug patent does not receive notice from the applicant for generic drug products registration, but the patent holder finds infringement of its patent. The patent holder can also bring a patent infringement action in the court and notify the drug review institution.

The CFDA experimentally defined the patent linkage system in the drug marketing approval process in the Drug Registration Regulation enacted in 2002, which was later revised in 2005 and 2007. However, the Drug Registration Regulation did not

clearly say whether the patent holder of the relevant drug can bring a patent infringement action against the generic manufacturers. Under Article 18 of the Drug Registration Regulation, disputes over patent right arising during the process of drug registration shall be resolved pursuant to the relevant patent laws and regulations. The lack of clarity in such a system can damage the effectiveness of such a system, resulting in harm to both innovators and generic manufacturers. The innovators are facing generic competition prior to the expiration of their valid patents. The generic manufacturers are facing lengthy and costly patent infringement litigation after they launch their drug products.

However, China later developed and introduced the Bolar exception system of US patent law into Chinese patent law system by both case law and statute. Under Article 69 of the 2008 China Patent Law, there should be no patent infringement issue in the drug registration process. In addition, under Article 19 of the Drug Registration Regulation, the generic manufacturers can file a drug registration application with the CFDA within two years prior to the expiry of such drug patent. Thus although the current laws do not say whether the innovators can file a patent infringement action with the court against generic manufacturers' pre-market infringement, based on the above analysis, it's not practical for innovators to initiate such patent lawsuits under the current legal schemes.

Compared with the current legal schemes, the Policy No. 55 has made significant progress on this. The Policy No. 55 provides a cause of action to sue prior to market entry based on the act of seeking marketing approval other than waiting a generic drug to be on the market in order to constitute infringement under the current laws. Furthermore the laws might explicitly distinguish between the generation of data for marketing approval (a non-infringing act) from submitting that data for the marketing approval and subsequently entering the market (a potentially infringing act), thereby allowing patent holders to initiate patent infringement actions based on submitting data for marketing approval and providing an avenue to prevent infringing drug products from entering the market.

However, to fully implement the Policy No. 55, a number of laws or regulations and judicial practices need to be changed. For example, the 2008 China patent law needs to be revised that marketing approval application for generic drug products covered

by innovator's patents may constitute infringement. In addition, it is also unclear what courts may have jurisdiction over such matters.

Comparing with the Drug Price Competition and Patent Term Restoration Act of 1984 in the US, also known as the Hatch-Waxman Act, the patent holder in China who receives a notice under scenario I only has 20 days to file a lawsuit, which is much shorter than 45 days prescribed in the Hatch-Waxman Act. Generally speaking, preparing a patent infringement case particularly in the pharmaceutical area is complicated and time consuming. Thus the 20-day case preparation period might be a challenge for innovators particularly for international big organizations which would usually involve complex and lengthy internal decision-making process for initiating a patent infringement lawsuit.

24-month Approval-withholding Period

Under Article 1 of the Policy No. 55, the CFDA may set an approval-withholding period up to 24 months if the patent holder of relevant drug patent files a patent infringement action with a court, during which period, the technical review of any drug already under review will not stop. During the approval-withholding period, if the innovators and generic manufacturers settle the dispute or if the court renders an effective judgment finding infringement or non-infringement, the CFDA should grant or deny drug marketing approval based on the settlement between them or the relevant effective judgment by the court. At the end of the approval-withholding period, if the court has not rendered a judgment finding infringement, the CFDA can approve the drug marketing.

Under the Hatch-Waxman Act, the FDA's approval-withholding period is 30 months. Actually the 24-month or 30-month approval-withholding period should not really matter for protecting the innovator's interests from business perspective. However, in view of the heavy workload of Chinese courts, it might be a challenge for Chinese courts to make final decisions on determination of the patent infringement within 24 months in pharmaceutical area particularly if a party is foreigner. According to the above regulations, if the court fails to find the infringement within the 24-month approval-withholding period, the CFDA can approve the drug marketing. However there is a practical risk for this scenario. If the court eventually finds the infringement but renders the judgment far beyond the 24-month approval-

withholding period, how will the CFDA deal with the approved generic drug marketing particularly where the generic manufacturers have significantly launched the drugs?

In addition, different from the US patent linkage system, the Policy No. 55 does not involve patent validity issue. In China, the court does not have the jurisdiction to determine the validity of patent at issue in a patent infringement case. The validity of patent at issue should be subject to the decision of the Patent Re-examination Board of State Intellectual Property Office (the "PRB"), which is available to be appealed to the courts. Thus there might be such scenario where the court finds infringement and the CFDA denies the drug marketing within the 24-month approval-withholding period, but the patent at issue is eventually invalidated, how will the CFDA deal with such problem?

Therefore, it appears that there are still some pending issues to be further clarified in relation to the 24-month approval-withholding period. Both the innovators and generic manufacturers should concern the uncertainties arising from these pending issues because they might much affect their businesses.

Available Notice System for Innovators

The China's current experimental patent linkage system has been lack of a mechanism to timely notify patent holders of the pending applications for potentially infringing drugs with the CFDA. Under Article 1 of the Policy No. 55, CFDA would develop a mechanism for identifying patents that are relevant to applications for marketing approval for drugs, including by notifying the patent holders of such pending applications.

The Policy No. 55 provides that the generic manufacturers need to notify the patent holder of the relevant drug patents within 20 days after filing the generic drug products registration application with the CFDA. However, it fails to say what liabilities the generic manufacturers should bear if they fail to notify the innovators. We understand that the innovator might bring a patent infringement action against the generic manufacturers in the court at any time if the generic manufacturers fail to notify the innovators of the generic drug products marketing application with the CFDA. This genuinely would not substantively affect the interest of the generic

manufacturers. Thus it is doubtable for the generic manufacturers would honestly, completely and timely notify the innovators of such application.

Generic manufacturers' Disclosure Obligations

The Policy No. 55 provides that the generic manufacturers for generic drug products registration application should submit a statement on the relevant rights involved that they know or should have known upon filing such application as well as a non-infringement statement. However, the potential problem is that the reliability of the statements submitted by the generic manufacturers. The generic manufacturers are required to submit the status for relevant drug patents and non-infringement statement, but are not required to provide a relevant patent search report and non-infringement statement reviewed by qualified professionals.

Actually the current Drug Registration Regulation has required that applicants for marketing approval for generic drug products identify relevant and unexpired patents upon filing applications for marketing approval with the CFDA. The applicant should provide a description of the ownership status of relevant patents. If the drug is patented by others in China, the applicant shall submit a non-infringement statement. But the current system lacks of a mechanism to ensure that an applicant seeking marketing approval for generic drug products has completely and accurately identified all relevant current patents in its marketing approval application, thereby results in inaccurate or incomplete patent references in such applications, leading to CFDA granting marketing approval to potentially infringing generic drug products. Thus it appears that the Policy No. 55 has not resolved the issue to make sure that the generic manufacturers honestly, accurately and completely fulfil their disclosure obligations.

Chinese Version of Orange Book

Under Article 3 of the Policy No. 55, the CFDA would compile a catalogue of marketed drugs products which should be similar to Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") published by the FDA of US. For all drugs listed, the catalogue would specify the active pharmaceutical ingredients, the dosage forms, the specifications, the holders of the marketing licenses, and information on exclusive rights such as patent involved, monitoring

period, and data protection. It would also specify the properties of innovative drugs, improved new drugs, and generic drug products that have passed the evaluations for quality and bioequivalence.

The Chinese version of Orange Book should play important roles for the CFDA's contemplated patent linkage system. This increases the clarity and transparency for all parties concerned. First, the system allows generic manufacturers to be well aware of any possible patents covering the generic drug products for which they wish to seek marketing approval. Armed with this information, a generic manufacturer can devote resources to other products, choose to wait until the relevant patents have expired, or even challenge the validity of the relevant patents if they so choose. Thus the system would make the business decisions of the generic manufacturers more predictable. Second, the innovators might proactively prevent their patents from infringing by the generic manufacturers under such a system. Third, the CFDA and courts might make sound judgments on whether the innovators unfairly prevent the generic manufacturers entering the market through patent misuse according to the patents coverage in relation to the generic drug products.

Concluding Summary

The Policy No. 55 is a welcome breakthrough to the growing patent linkage system in China. It introduces several fundamental systems into the developing patent linkage system in China, but it also remains a few important pending issues to be clarified. To fully implement the Policy No. 55, a number of laws and regulations like the patent law needs to be amended accordingly. It is much too early to tell how effective a tool the Policy No. 55 will be for the purpose of encouraging and protecting innovation in the pharmaceutical industry as stated in it, but it is certainly a good start to more effective and efficient patent enforcement in China due to the effective IPR protections provided by both the patent system and the regulatory system. They provide a "linkage" between the drug regulatory approvals and patent infringement, whereby regulatory approval is denied until the relevant patent is determined to be not infringed.

It is certain that the Policy No. 55 would have significant implications on both the innovators and generic manufacturers. For generic manufacturers, they should attach importance to the patent coverage in relation to the generic drug products

while making their business decisions to avoid possible risk of patent infringement. The Policy No. 55 still might lack a sound mechanism to make the innovators be timely, completely and accurately notified of the pending market approval applications for the generic drug products, the innovators should actively and regularly monitor the information regarding the pending market approval application for the generic drug products and proactively take advantage of the patent linkage system.