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CHINA'S PATENT LINKAGE SYSTEM FOSTERS INNOVATION, KEEPS GENERIC MAKERS IN FOLD

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While the recent decision to implement a patent linkage system in China seeks to encourage innovation in the pharmaceutical industry, manufacturers of generics could also stand to gain from it.

The Chinese Food and Drug Administration said May 12 that it plans to link the application process for new drug approval to patent rights, and that pharma companies seeking market approval for new drugs will have to declare whether their products violate intellectual property rights.

Yahong Li, associate professor at the University of Hong Kong's law department, said in an interview that there are terms in the policy draft which, if not clarified in the final policy, could be interpreted by generic drug manufacturers to their advantage.

For example, how do you define who is an innovator?

"The policy states its purpose is to protect innovators' rights, but who are these innovators? Would a company developing a drug based on an existing product be considered an innovator as well?" Li, who specializes in intellectual property law, said.

Also, the time given to patent holders to file a lawsuit against the generic manufacturers infringing on their patents is shorter compared to the U.S., Li pointed out.

### **Moderate link**

Under the proposed patent linkage system, patent holders in China who receive a notice of infringement have 20 days to file a lawsuit, while in the U.S. they have 45 days. The holding period, when regulators halt the market approval process and wait for courts to sort out disputed patents, would be 24 months in China, while in the U.S. it is 30 months, Li added.

So while the new policy aims to establish a connection between patent status and the drug approval process, the link is seen to be "moderate" by Li because the turnaround time for approving generics is shorter than in the U.S.

A patent linkage system typically delays generics reaching patients who require them most,

she said. "By introducing a moderate linkage system, it might be the aim of the regulator to strike a balance between protecting patent holder rights while still introducing generics to market at a steady pace," she said.

The policy also seems to "encourage generics to challenge the innovator's patent," as it stipulates that the "first successful challenger will be eligible for 18 months exclusivity," according to a report on Lexology by Allen & Overy LLP lawyers David Shen, Dylan Ding and Jill Ge.

The exclusivity is likely against other generic applicants, the report added.

"The newly announced policy document confirms the regulator's intentions to enhance patent linkage by requiring the drug review authority to take into account patent infringement disputes during its review process of the market authorization," Caroline Wong, an associate at international law firm Bird & Bird, said in an email.

The linkage system will prevent the CFDA from approving a product that would violate a valid patent, she said.

This is the first time the CFDA has linked patent rights to the market approval process, the Lexology report said.

"At the moment, there isn't a requirement in the Chinese system for an applicant to notify the patent holder about any infringements, so the linkage system is an improvement for patent holders," said the University of Hong Kong's Li.

The policy draft also proposes 10 years of data protection for new orphan or pediatric drugs and six years of data protection for other new drugs, according to the Lexology report.