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China has proposed offering attractive exclusivities to foreign companies to encourage earlier clinical testing and importation of innovative drugs in China. Find out the details in this article.

China IP Developments in Biotech/Pharma
New Policies to Promote Importation of Innovative Drugs

At the April 12, 2018 executive meeting of the State Council in China, Premier Mr. Li Keqiang indicated the government's desire to increase China's access to innovative drugs. To achieve this, the government would encourage importation of innovative drugs into China by streamlining the regulatory pathway, enhancing IP protection, and lowering the cost of medicine. Shortly thereafter, the Chinese Food and Drug Administration (CFDA) published draft guidelines on May 12, 2018 and asked for comments. Below is a summary of where things stand today.

Patent Linkage

China is proposing a "patent linkage system" similar to that of the US. It is the first time that China has "linked" an innovator's patent rights directly with the generic drug approval process.

The proposed law would require all new generic applicants to make a non-infringement or invalidity declaration against patents covering the original drug and notify the innovator of its generic application within 20 days of filing. The innovator must commence suit within 20 days of receiving the notification in order to trigger a 24-month stay of the generic applicant's drug approval. This stay can be terminated if the generic prevails in a patent lawsuit or the parties reach a settlement.

Eagle Thoughts: *20 days is a short amount of time to gather all necessary evidence needed for submission with the filing of a lawsuit. Unlike in the US where there is a long extended discovery process, Chinese litigations are quick, efficient, and require submission of at least some acceptable evidence at the start of the trial. There is still question about what 20 days means, especially in light of China's historical acknowledgement of an extra 15-day "mailing" grace period.*

In view of such tight turnaround times, we encourage companies to be prepared for potential litigation well before a first lawsuit appears from a generic company.

Chinese "Orange Book"

The CFDA has published its first Catalog of Approved Drugs (similar to the Orange Book in the US) in December 2017. Most importantly, this book will list related patent and data exclusivity information for innovative and generic drugs, allowing everyone to know which patents need to be listed in a new generic drug application.

Data Exclusivity

China currently offers data exclusivity for new chemical entities (NCEs). The CFDA's newest proposed guidelines extend protection to cover innovative drugs, innovative biological treatment products, orphan drugs, paediatric drugs, and drug products that have succeeded in a patent challenge ("first generics"). Applicants can receive up to 6 years of data exclusivity for new chemical entities and up to 12 years for orphan diseases, paediatric diseases, and biologics. Existing drugs modified for orphan or paediatric use can receive 3 years.

First generics who successfully challenge an innovator's patent can receive 18 months data exclusivity for their own clinical trial and bioequivalence data, provided that the original drug was not already approved in China.

The draft guidelines limit data to preclinical and clinical data related to drug efficacy, not safety. Furthermore, the data used must satisfy the following requirements:

(1) required by the agency as part of a marketing authorisation application
(2) not publicly disclosed prior to the drug application submission, and
(3) independently developed without reliance on data by others

Most importantly, the maximum exclusivity period can only be met if the applicant **uses data from an international multicentre clinical trial in China or a clinical trial in China** and **files the drug application in China first or simultaneously with applications in other countries**.

The exclusivity period is reduced to 25% if the drug application only relies on data outside of China with no Chinese patients. This amount can be raised to 50% if the application is supplemented with clinical trial data with Chinese patients. For orphan and paediatric drugs, the exclusivity period is 6 years regardless of source of data and timing of grant.

For applicants who file for approval in China after filing in other countries, reduced exclusivity periods of 1 to 5 years are available, up to six years later, after which no data exclusivity is available. If the applicant fails to put the product on the market within 1 year of approval in China, data protection can be challenged and revoked.

Generics who want to apply for approval using their own clinical data must make a declaration that the data are their own, and they must send the data to the innovator. The innovator can rebut if the innovator disagrees.

Eagle Thoughts: *If these draft regulations are adopted, companies who want to enter the Chinese market should strongly consider including China in their international multi-centre clinical trials. Even prior foreign filers of NCEs who currently enjoy 6 years of data exclusivity may in the future only receive 25% of that unless if they run a simultaneous clinical trial in China.*

Patent Term Extension

The State Council in China announced its intention to extend patent protection up to 5 years due to regulatory delay. No other details have been given, and no law changes have been made. It is likely that any such changes would take several years to be implemented, and the extensions would only be available to patents filed after the law change takes place.

Additional Streamlining Measures

The government will streamline the regulatory pathway for imported medicines, allowing chemical medicines to rely on testing results of enterprises and removing compulsory testing by batch. China has removed customs duty for all common medicines, including all cancer therapeutics. Finally, the government indicates it will take a number of measures to lower drug prices while increasing quality.

Eagle Thoughts: *Clearly, China wants to encourage foreign companies to run earlier clinical trials in China and has proposed significant incentives. Companies developing global IP strategies for drugs that may enter China should definitely consider the additional IP protection from data exclusivity, patent term extension, and stays offered by the proposed changes. We think it is very important to continue considering these alternate forms of IP protection as part of an overall broader IP strategy for the protection of drugs in this ever-changing Chinese landscape.*

CFDA Policy: Official Chinese Version

We will keep you updated for further development. Stay tuned for more important updates on IP law in China.

Please contact us with any questions: eip@eipgroup.asia.

Eagle IP are experts in patent law and we offer a one-stop service for your global IP needs.