New China Patent Linkage System for Pharmaceuticals and Biologics

Executive Summary

The new China regulations on patent linkage implement a system which is similar to the Hatch-Waxman Act in the US. Under this new system, innovator drug companies can finally stop generics obtaining market authorisation before patent expiry. However, to obtain such protection, companies must notify the Chinese drug authority their patents within 30 days of their products obtaining market authorisation. Also, once the companies find out about the generics’ market authorisation applications, they have less than 45 days to commence action to stop the generics. Companies need to prepare well in advance in light of the short timeframes.

Details

When innovator drugs are granted market authorisation, their patent terms usually have only half left, e.g. about ten years out of the 20 years left. In addition, before China has the patent linkage system, the Chinese drug authority would grant market authorisation to generics even though the relevant patents are still in effect.

Under the new patent linkage system, to obtain the protection, an innovator drug company must list its patent(s) within 30 days of its product obtaining market authorisation in China. If that is done, when a generic company applies for market authorisation, the generic company must notify the innovator company. The innovator company must within 45 days of the generic application being published on the website of the Chinese drug authority (https://zldj.cde.org.cn/home) commence a case to stop the generic’s application for nine months. In addition, the innovator company may seek an injunction to prohibit the generic being put on the market before the expiry of the patent(s).

The following products are covered by the new patent linkage system:

(i) chemical drugs (compound patents of active ingredients, composition patents containing active ingredients and indication patents);
(ii) biologics (sequence structure patents of active ingredients and indication patents); and
(iii) traditional Chinese medicine (compound patents, medicine extract patents and indication patents).

Of particular note is that the nine-month suspension of the product registration process is only available to chemical drugs, not to the other two types of products above.

Under the new law, generic drug companies would likely commence invalidation proceedings against the relevant patents to obtain market exclusivity and to accelerate their product registration process.

In light of the tight timeframes, innovator companies need to be well prepared as soon as possible, including selecting certain patents for patent linkage, preparing the defence of the validity of their patents and monitoring the publication of generic applications, while coordinating their global strategy.
On the other hand, the first generic drug company that successfully challenges the validity of a listed patent for a chemical drug and obtains market authorisation will be granted an up to 12-month market exclusivity period. Such market exclusivity period does not exceed the patent term.

To capitalise on this new opportunity, generic drug companies need to act fast. A generic drug applicant therefore may consider commencing invalidation proceedings against the relevant patents to obtain the market exclusivity and accelerate its product registration process.
Let’s talk

For a deeper discussion of how this impacts your business, please contact us. Our China patent litigation team has worked for many years with the European and US life sciences companies and industry organisations to lobby for introducing patent linkage in China.

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