# Major IP reforms foreshadowed in China's Pharma sector

**A more robust patent linkage system and data exclusivity regime to be established by the CFDA**

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## A more robust patent linkage system and data exclusivity regime to be established by the CFDA

*On 12 May 2017, the Chinese Food and Drug Administration (the "CFDA") issued several draft policies aimed at overhauling of the current regulations governing the Chinese pharma and medical device sector (the "Draft Policies"). Amongst the Draft Policies, those outlined in Circular No.55 would, if implemented, establish a more robust patent linkage system, a more extensive data exclusivity regime and create a Chinese version of the US Orange Book. In this client alert, we highlight some of the proposed changes.*

### 1. Current Patent Linkage System in China

The idea of patent linkage is that the marketing approval for a generic drug is "linked" to the expiration or invalidation of the originator's drug patent.

Under the Provisions for Drug Registration (CFDA Order No.28) ("**the Provisions**"), an applicant for drug approval should provide information on the patent and its ownership with respect to the drug product, its formula, manufacturing process and/or uses. Further, the drug approval applicant must make a declaration of non-infringement. For a drug patented in China, an applicant other than the patentee may submit an application for drug approval up to two years prior to the expiry date of the patent but the CFDA will not issue the marketing authorization until the expiry of the patent in issue.

Some problems inherent with the process outlined above have weakened the effectiveness and strength of the existing patent linkage system. First, the Provisions rely on the drug approval applicant itself determining whether or not the product is covered by a third party's patent. Neither the CFDA nor the patentee or any other independent parties can take part in this determination process. Accordingly, it provides the potential for lack of objectivity or manipulation. Further, the Provisions fail to prescribe the consequence for non- compliance. As a result, many market authorization applications for pharmaceutical products do not provide the required patent information. This has compromised one of the goals of patent linkage system, which is supposed to promote patent information transparency for both the originator and a generic applicants' benefit.

### 2. Proposed Patent Linkage System

According to the proposed new patent linkage system, each drug approval applicant must file a statement containing a list of patents that the applicant knows or should know cover the drug.

In addition, the drug approval applicant must notify the identified patentees within 20 days from the submission of the application. The notified patentees can then, in turn, file infringement litigation if they believe the drug infringes their patent, within a 20 days' timeline.

The involvement of the judiciary, who are better equipped to determine patent infringement issues than the drug applicant themselves, is expected to introduce neutrality and legal certainty to the proposed linkage system.

As soon as the CFDA is informed of any ongoing infringement litigation, it can decide to suspend its formal review of the application for up to 24 months. Meanwhile, the technical review may still continue during the period of any suspension. If a final court decision is handed down (or a settlement is reached) within the suspension period, the CFDA will, accordingly, either grant or reject the application. If the infringement case is not concluded within 24 months, the CFDA can decide to grant the marketing authorization, even though the infringement procedure is still pending.

A prominent feature of the proposed system is that if the applicant fails to provide the relevant

patent information in the drug approval filings, a patentee may still bring a lawsuit and the CFDA can suspend the application for a maximum of 24 months. The patentee can thus take a more proactive approach to prevent market entry of infringing products. This more adversarial model will give the patent linkage system more "teeth" than before.

It is generally hoped that this proposed patent linkage system will increase the legal certainty for both originators and generics companies by publicizing relevant patent information and involving the courts in determining patent infringement at the early stage of the drug approval process. This new patent linkage system also offers a better balance between drug innovators and generics companies by allowing originators to play a more proactive role.

## 3. Proposed Data Exclusivity Regime

The new Draft Policies in Circular 55 also propose a more comprehensive regulatory data protection regime for pharmaceutical products.

Data exclusivity provides additional market exclusivity to innovative companies independent from the patent system. According to Article 20 of the Provisions, the confidential and independently acquired experimental data and other data submitted by manufacturers or distributors of drugs containing new chemical entities will be protected for up to six years from the marketing authorization of the originator drugs by the CFDA. During this period, the CFDA will reject any applications made by subsequent developers using the same data about the drug without the permission of the applicant who originally submitted the data, unless the data submitted by others are independently acquired. The subsequent developers include generic or biosimilar companies who will need to prove equivalencies to the originator's drugs.

Aiming to encourage and reward innovations, the Draft Policies would further extend the period of data protection from six to ten years for innovative orphan or pediatric drugs, and innovative therapeutic biological products.

The data regarding existing drugs that are modified for the treatment of orphan or pediatric diseases may also benefit from a renewed protection period of three years.

Moreover, the Draft Policies contain a 'priority regime': clinical data for drugs approved in Europe, the US or Japan may benefit from the data exclusivity periods if the drug approval request is filed in China within one year after obtaining these foreign drug approvals. If the drug approval request is filed in China more than one year after obtaining the foreign drug approval, the data exclusivity period will be reduced by the period in excess of one year, but the exclusivity period shall not be less than 18 months.

Finally, the first generics company that manages to successfully challenge a Chinese pharmaceutical patent for a drug approved abroad may also be granted an 18 month data protection period, as an incentive for generics companies to try and invalidate Chinese pharmaceutical patents and thereby reduce the cost of certain patented drugs.

## 4. China's 'Orange Book'

Similar to the 'Orange Book' in the USA, the Draft Policies propose the creation of a "Catalogue of Approved Drugs", which would contain details about approved drugs and their active ingredients, patents and regulatory exclusive rights etc.

This would be step in the right direction, as it would greatly increase the transparency regarding approved drugs in the PRC.

## 5. Some observations on the Draft Policies

There appear to be welcome reforms on their way in the pharma sector, as signaled by the Draft Policies.

The proposed patent linkage system and the data exclusivity regime, if implemented, are expected to give more incentives to innovative companies whilst adjusting the information asymmetry for generic companies. Since the Draft Policies are general guidelines only, detailed regulations implementing such policies are forthcoming.

The Draft Policies, although having similarities to the U.S. model, have their own distinct features. For examples, with regard to the patent linkage system, they require the patentee to react within 20 days from the receipt of notice from the drug approval applicant. Such period is 45 days in both the U.S. and Canada. The 20 days period may pose challenges for a patentee to react, collect evidence of an infringing act and prepare infringement pleadings in time. This may be a particular issue when the plaintiff is a foreign entity, as the legalization and notarization process required by PRC Civil Procedure Law typically takes more than 20 days.

The proposed suspension period is 24 months in China whereas it is 30 months in the U.S (although this period can be shortened or extended by a court). In Canada, the suspension period is also 24 months but the court proceedings for determining whether or not to grant the market authorization are only summary in nature and the losing party does not have a right of appeal. According to the Draft Policies, the CFDA shall make a decision according to an "*effective*" court judgment. Under Chinese law, a judgment normally takes effect when the parties exhaust their right of appeal. Further, since patent infringement and invalidation proceedings are bifurcated in China, the proceeding may be further prolonged for a pending invalidation action at the State Intellectual Property Office. Such considerations together may argue for a longer suspension period than the Draft Policies contemplates.

## 6. Conclusion

The Draft Policies propose a far-reaching modernization of the current regulations, and attempt to ensure a better balance between innovative pharmaceutical drug companies, medical institutions conducting trials and generics companies.

The Draft Policies seem to draw heavily on systems that have produced good results abroad, and it will be interesting to see how they may improve the current Chinese pharmaceutical regulations.

Many of the concrete implementation details are currently not yet finalized. The CFDA requested comments from stakeholders in the industry by June 10. After analyzing the comments, the CFDA may either adopt the current Draft Policies as they stand, or revise the drafts and publish new versions for another round of comments.

We will keep you updated of any new developments.

In the meantime, should you have any questions, please do not hesitate to contact our lawyers listed below.

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