

Sonderhoff & Einsel News Update: China IP Newsletter (December 2017)

Update of Patent Linkage System for Pharmaceutical Products in China

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Update of Patent Linkage System for Pharmaceutical Products in China

Patent linkage is a system where a country links drug marketing approval of a generic drug to the status of the patents related to the originator's product. In China, there have been a series of regulations that have been released for public comment which indicate that China will soon be introducing a patent linkage system: on May 12, 2017, the China Food and Drug Administration (CFDA) announced for public comment "Policies regarding the Promotion and Protection of Innovators' Rights in Pharmaceutical Products and Medical Devices" ("Announcement No. 55"); 2) on October 8, the General Office of the CPC (Central Committee) and the General Office of the State Council of the People's Republic of China published an "Opinion on the Promotion of Reformation regarding Examination and Approval System as well as Innovation of Pharmaceutical Products and Medical Devices" ("Opinion") for extensive implementation of reforms; and 3) on October 23, the CFDA released for public comment "Administration Regulations for Registered Pharmaceutical Products" ("Proposal for Revision").

This system hopes to ensure a stable supply of pharmaceutical products by taking the patent term of an original drug into consideration by, for example, negotiating with the original drug manufacturers prior to the approval of generic drugs. Since 2007, generic drug applicants are obliged to declare that their generic drug products do not infringe the patent right of the original drug. However, there is no mention of the punishment or penalty for non-conformance with this obligation. Since the CFDA is not capable of examining whether the generic drug infringes a patent right in response to the approval application for generic drugs, it is highly probable that the CFDA will approve the generic drug without clarifying the possibility of patent infringement. The linkage system will attempt to resolve these issues, but as commented below, the new set of regulations will still be insufficient and advantageous for generics as a whole. Therefore, generic drug manufacturers are expected to mount a more vigorous challenge to original drug manufacturers' patent rights and original drug manufacturers are expected to file lawsuits in response to these challenges. Thus, disputes regarding patent rights are likely to increase further after introduction of the patent linkage system.

We would also like to briefly comment on the new legal regulations.

1. Inventory of Pharmaceutical Products Approved for Marketing in China ("Chinese Orange Book")

According to the "Announcement No. 55" and "Opinion", the authorities have prepared an inventory of pharmaceutical products newly approved for marketing as generic drugs which have passed an evaluation with respect to the quality and therapeutic effects identical to the original drugs.

Our comment:

In practice, the "Publication of Patent Information Regarding Approval of Pharmaceutical Products" (<http://eng.sfda.gov.cn/WS03/CL0755/>) is often used by generic drug manufacturers when non-infringement of a patent right needs to be confirmed. However, this website is sometimes not comprehensive or reliable, and thus additional research using a patent search system of SIPO or commercial database, or expert opinions are often required. Accordingly, the Orange Book has been

created, and it is expected that generic drug manufacturers and the CFDA will refer to the patent information provided in the Orange Book.

2. Statement regarding non-infringement of patent right

According to the "Announcement No. 55", "Opinion" and "Proposal for Revision", an applicant of a generic drug needs to notify the patent proprietor of the original drug when applying for marketing approval of pharmaceutical drugs of the relationship between the generic drug and the patented invention of the original drug manufacturer.

Our comments:

None of these regulations mentions any punishment or penalty for non-compliance. Also, the regulations do not specify how the generic manufacturers should notify the patent proprietor of their applications, whether the patent right is deemed to be infringed when the notification is insufficient, or what kinds of measures can be taken when a judgement of infringement is difficult to obtain. Concrete regulations related to marketing approval of a drug by SDFA are expected to clarify these issues.

3. Challenge to patent rights

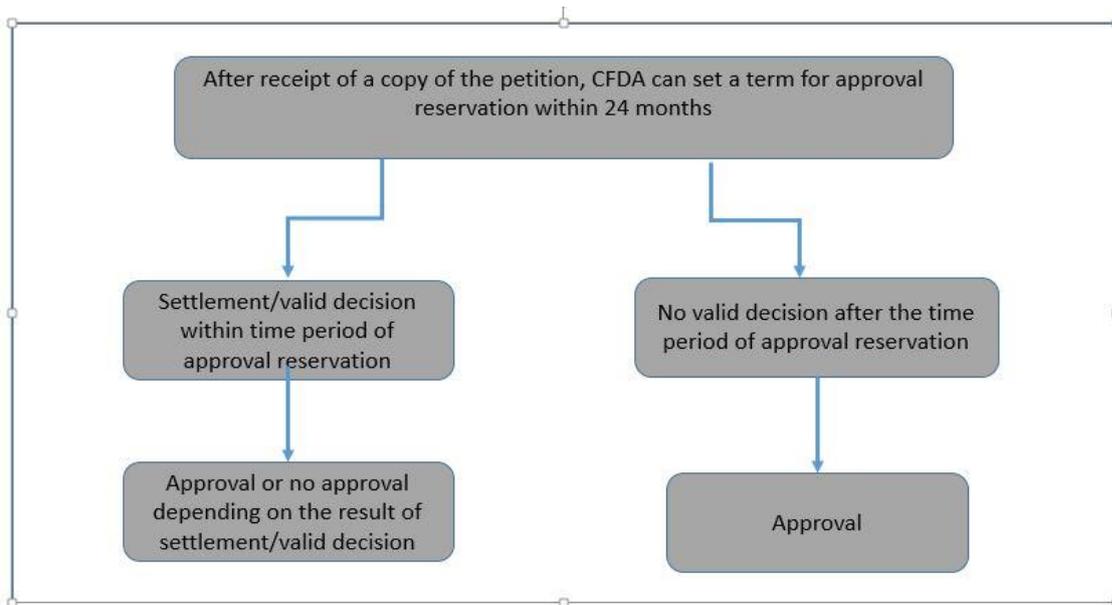
According to "Announcement No. 55", when generic drug manufacturers want to nullify an original drug patent right, they need to notify the patent proprietor of the non-infringement of their generic drug within 20 days from the submission of the request for the generic drug approval. In response, the patent proprietor needs to file an infringement suit before the court within 20 days from the receipt of said notification and inform the CFDA accordingly.

Our comment:

A practical way to challenge a patent right is to request a patent invalidation trial before the Patent Re-examination board of SIPO. The twenty-day period for the patentee to file a patent infringement suit from the receipt of the notification is, however, completely insufficient, considering the time required to collect relevant evidence and obtain a notary certification or similar items. A more flexible rule with respect to these deadlines for patent proprietors residing abroad should be considered.

4. Time period of approval reservation

According to "Announcement No. 55", the CFDA must issue a decision as to whether or not to approve the application for generic drugs.



Our comment:

If no valid judgement is given within the prescribed time period, the CFDA can approve the application by the generics. Therefore, it is predicted that generics will try to delay the lawsuit beyond 24 months by every means available. Thus, the above provision is currently advantageous for generics.

5. Protection period of experimental data

According to the "Announcement No. 55" and "Opinion", the applicant of an original drug may request data protection together with the application for approval. Time periods for protection of drugs are from 1.5 to 10 years depending on the type of drug and whether they are new or have been marketed abroad but are to be launched in China for the first time as generic drugs. During this period, applications for identical items by other applicants will not be approved.

Our comments:

A data protection period could be regarded as an exclusive right for product marketing. However, there are still no clear answers to questions as to whether a data protection period will be granted on pharmaceutical products whose applications have been received by the CFDA before the announcement of the opinion and are not yet approved, or to which companies a data protection period will be granted if several generic drug manufacturers challenge a patent right. Concrete actions are expected.

6. Adjustment of patent protection term for pharmaceutical products

According to the "Opinion", the authorities will create a trial system to allow for an extension of the patent protection term for some new drugs if the patent proprietor files an application for adjustment of the patent protection term for new drugs due to the protection time it loss during the approval process of an original drug in CFDA.

Our comment:

The Chinese Patent Act stipulates that the term for protection of patent rights with respect to drugs is 20 years which is calculated from the filing date. However, with this new system, an original drug maker can apply for an extension of the patent protection term, for example, for an additional five years if it the CFDA's approval process of the drug took such an amount of time. However, the introduction of a patent term extension system for patent rights relevant to pharmaceutical products is not yet realistic in China. A lot of opinions opposing this system were heard for the sake of public interest and which new drugs can be the subject matter of the system or how the term should be compensated is yet to be decided.

7. Bolar Provision

According to a provision of the "Announcement No. 55", the patent proprietor of a new drug must file a patent infringement lawsuit before the court if the applicant of a generic drug approval infringes his patent right.

Our comment:

However, the Chinese Patent Act Article 69, Paragraph 5 stipulates that manufacturing of patented pharmaceutical products or medical devices solely for the purpose of obtaining necessary information for the approval by the CFDA will not be regarded as an infringement. In China, since there is no provision like the Hatch-Waxman Act, patent proprietors may not be able to file a patent infringement lawsuit against applicants of the generic version of its drug.

About us

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