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A Prospect on Protection of Innovative Drugs Post US-China Trade Agreement

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The United of States and the People's Republic of China reached the milestone Economic and Trade Agreement (the "***Agreement***") on 15 January 2020. Chapter 1 on protections of intellectual property rights forms an important part of the Agreement and the terms on protections on innovative drugs constitute an important part of Chapter 1. When the Agreement is fully implemented, the landscape of intellectual property protections for innovative drugs will change significantly and innovative pharmaceutical companies' interest will be better protected.

Nature of Agreement

The Agreement, in its nature, is a bilateral agreement between the United States and the People's Republic of China. It largely contains commitments which China makes to improve its intellectual property protection systems and to further open up its market. Different from other international treaties of which the provisions are largely principles, the Agreement comprises of explicit steps which China will take within a stipulated period of time. Measures are also included to ensure that China will take these steps as it commits to. Therefore, from the signing of the Agreement, the government's actions towards the implementation of the Agreement, including the legislations and enforcement actions as discussed below are foreseeable.

It is worth noting that, although the Agreement is bilateral, it will have impact on trading relationships between China and other countries. A significant number of the provisions in the Agreement require China to improve its legal system and trading practice. These improvements are not targeting United States and will benefit foreign investors as a whole. Moreover, when the Agreement was announced, the China government made a public statement that the Agreement is in line with the orientation of economy reformation of China. In other words, these improvements which China commits to are largely what China is willing to do by itself. Consequently, China is not to improve its legal system and to open its market just for the United States but for its own benefits and for the interest of general foreign investors.

Requirements on Protections of Innovative Drugs

In relation to protection of innovative pharmaceutical business, the Agreement has provisions to improve legislations to render better protections on intellectual properties and to enforce such intellectual properties more robustly.

1. Consideration of Supplemental Data

Under Article 1.10 of the Agreement, China is required to permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability, including sufficiency of disclosure and inventiveness step, during patent examination proceedings, patent review proceedings, and judicial proceeding. This position changes from the current patent prosecution system where supplemental data are admissible in only very limited circumstances.

According to Article 69 of the *Implementation Regulation of the PRC Patent Law*, descriptions, which are used to describe inventions, are, generally speaking, not allowed to be amended after the submissions. The currently effective Patent Examination Guidance, although allows the submissions of supplemental experimental data, the data are admissible only if normal technicians in the area are able to generate these data from the submitted description. In other words, these data are a natural conclusion from what has already been included in the description without significant experiments or inventive steps.

The restriction on submissions of supplemental data is reasonable vis-à-vis most business sectors as it permits patent applicants to claim for protections on what they have discovered on or before patent filing dates. However, it creates difficulties for innovative pharmaceutical companies. In the pharmaceutical sector, taking chemical drugs as an example, although functionalities of a drug in human-being can only be proved during clinical trials, companies tend to apply for patent protections at an earlier stage when a compound is discovered and an indicative usage is identified. This approach helps secure patent protections on the relevant compound and its usage but there is a risk that the experimental data generated at the patent filing data are not sufficient to demonstrate the functions. Existing cases show that quite a number of patents on pharmaceutical products (especially those which entered into China via PCT) have been invalidated because the data disclosed in the description submitted on the patent filing date do not form a sufficient disclosure. As a result, generic companies are able to produce copycat version of the innovative drugs of which the patents are invalidated.

By allowing pharmaceutical companies to submit experimental data generated after the filing of the patents, article 10 of the Agreement enables pharmaceutical companies to apply for patent protections earlier and then to continue experiments. Consequently, innovative pharmaceutical companies can receive earlier and more stable patent protections.

2. Earlier Resolution of Patent Disputes

With respect to the pharmaceutical regulatory related patent protections, the United States have established three important rules, being Bolar Exception, Patent Linkage, and Patent Term Extension. China has adopted the Bolar Exception, which allows generic pharmaceutical companies to implement innovative pharmaceutical companies' patents to generate data for the regulatory approval purpose. However, Patent Linkage and Patent Term Extension have not been introduced into China.

Article 1.11 of the Agreement aims to create a patent – regulatory approval linkage, by which a patent owner (1) will receive a notice when a generic pharmaceutical company applies for a regulatory approval for its generic drug by citing data concerning the safety and efficacy of the patented drug of the patent owner which has been previously approved and, then, (2) will have a chance to initiate a civil proceeding and to seek expeditious remedies for resolving the disputes concerning the validity or infringement of the patent prior to the regulatory approval of the generic drug. In other words, under Article 1.11, the patent owner does not need to wait for the commencement of actual marketing of the generic drugs to dispute on the validity or infringement of its patents vis-à-vis such generic drugs.

This patent – regulatory approval linkage system improves from the current regulatory approval system where applicants for regulatory approvals are supposed to voluntarily disclose the patent landscapes in relation to the drugs with respect to which regulatory approvals are applied for. In reality, such disclosures are neither accurate nor sufficient.

More importantly, the Agreement require China to create a cause of action to entitle patent owners to initiate legal actions to affirm the validity of their patents or to declare the infringement of generic drugs which are undergoing regulatory approval processes. This prospective entitlement is important because, according to the Bolar Exception, production of drugs falling within third party patents is considered fair use and not infringing during regulatory approval stage so that the court will rebut patent owners' claims without considering the substantive issues.

In light of the above, it is speculated that, when patent – regulatory approval linkage system is established, there would be increasing number of patent disputes initiated by patent owners before generic drugs are put onto marketing.

3. Effective Patent Term Extension

Patent rights grant patent owners exclusive right to implement the patents within a limited period of time. Under the PRC Patent Law, invention patent owners receive a 20 year protection period and utility model and design patent owners receive a 10 year protection period. The Agreement requires that China

provide for patent term extensions to compensate for unreasonable delays that occur in granting patents or during regulatory approvals for pharmaceutical products. Specifically, the Agreement requires the extension of patent protection periods in either of the following cases:

(1) in case of unreasonable delays, not attributable to patent applicants, that occur in patent prosecutions, at least including delays in issuance of patents of more than four years from the filings of patent applications in China or three years after requests for examination of the patent applications, whichever is later; and
(2) in case of delays in granting regulatory approvals for new pharmaceutical products or for methods of making or using new pharmaceutical products, which approvals are necessary conditions to marketing and sales of such products in China market, resulting in unreasonable curtailment of effective patent term.

In either of the cases above, China is required under the Agreement to adjust patent protection period so that patent owners can enjoy reasonable periods for exclusivity for marketing and sales its innovative pharmaceutical products in the China market.

The extension of patent protection period is particularly helpful innovative pharmaceutical companies which under a long way to obtain regulatory approvals for their innovative drugs. Like other major countries in the world, China requires pharmaceutical companies to perform strict pre-clinical trials and clinical trials before granting regulatory approvals, and it usually takes quite a few years to complete pre-clinical trials and clinical trials. Given that pharmaceutical companies typically apply for patent protections before or during pre-clinical trial stage to ensure the protections on their investment, it is not unusual that a quarter or even a half of the patent protection period elapses when they receive regulatory approvals. Consequently, innovative pharmaceutical companies receive inadequate period of protections.

China Food and Drug Administrative (***CFDA***) renders innovative pharmaceutical companies administrative protections in addition to patent protections. For example, under the Implementation Regulation to Drug Administrative Law, CFDA grants innovative pharmaceutical companies 6 years of data exclusivity, during which CFDA does not accept applications for regulatory approvals filed by using clinical data generated by innovative pharmaceutical companies as far as such data are kept in confidential. Additionally, for innovative drugs meeting certain criteria, they may receive monitoring period protections up to five years, during which CFDA does not accept applications for regulatory approvals for drugs containing the same active ingredients. However, comparing to patent protections, these administrative protections are short in durations and have more limitations.

The Agreement addresses this issue by extending patent protection period by no more than five years with maximum fourteen years from grant of regulatory approvals. As a result, innovative pharmaceutical companies may have longer period of patent protections and may have less concerns to apply for patent protections earlier.

4. Actions against Counterfeit Medicines

In addition to requirements on improving IP protections on innovative pharmaceutical products technically, the Agreement asks for strengthened enforcements against pirated and counterfeit goods, especially counterfeit medicines. The Agreement requires that the parties take effective and expeditious enforcement actions against counterfeit pharmaceutical and related products containing active pharmaceutical ingredients, bulk chemicals, or biological substances. In particular, China is required to take the following actions:

(1) to take effective and expeditious enforcement actions against related products of counterfeit medicines and biologics, including active pharmaceutical ingredients, bulk chemicals, and biological substances;
(2) to share with the United States the pharmaceutical raw material sites that have been inspected by the regulator and that comply with the requirements of Chinese laws and regulations, as well as any necessary information of relevant enforcement inspections;
(3) publishing online annually data on enforcement measures including seizures, revocations of business licenses, fines, and other actions, beginning within six months after the date of entry into force of this Agreement; and
(4) increasing the number of trained personnel to inspect, detain, seize, effect administrative forfeiture, and otherwise execute customs' enforcement authority against counterfeits (especially those exported and in transit) and, in principle, destroying the counterfeits seized.

These requirements aim to establish a comprehensive and robust enforcement system against counterfeit drugs. Firstly, the Agreement requires the expansion of effective enforcement from counterfeit drugs only to active pharmaceutical ingredients, bulk chemicals, and biological substances related to the counterfeit drugs. This creates a challenge task for the government as the government officials in market supervisory departments and in customs offices may be able to identify counterfeiting drugs but it would be difficult for them to distinguish active pharmaceutical ingredients, bulk chemicals, and biological substances. Secondly, the Agreement requires that China share with the US the information about pharmaceutical companies which passed inspections and relevant inspection data and publish enforcement measures online. This essentially allows the US government to monitor China's efforts in taking actions against counterfeit medicines. Thirdly, the Agreement asks to strength customs enforcement to improve customs officers' skills to identify and to destroy counterfeit medicines.

Consequently, it is expected that administrative and customs enforcement actions against counterfeits will be strengthened in terms of both the number of actions and the severity of the enforcement measures.

Conclusions

The signing of the Agreement is obviously a piece of good news for innovative pharmaceutical companies. It indicates that the intellectual property protections for innovative drugs have been almost upgraded to the level of developed countries. Such upgrade not only benefits multinational companies but also start-up companies engaging in developing new drugs in China. The overall business environment will be changed from "manufacturing" oriented to "innovation" oriented.

If you would like to know more information about the subjects covered in this publication, please contact:

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