



# WHITE PAPER: WEBINAR SERIES

Reciprocity Project: The Principle of Reciprocity  
BioPharma/Medical Industries  
2019

Anjie Law Firm - Beijing China  
Foreign Investment  
in China  
BioPharma Industry



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## China Adopts Foreign Investment Law March 2019

by Bo Hu, Partner - Anjie Law Firm

On March 15, 2019, China's national legislature, the National People's Congress passed the Foreign Investment Law (the "Law"), a landmark legislation that will provide stronger protection and a better business environment for foreign investors. The Law will take effective on January 1, 2020. Upon its effectiveness, the Law will replace China's current foreign investment regimes, i.e, the existing three laws on Chinese-foreign equity joint venture, the Chinese-foreign contractual joint venture and wholly foreign-owned enterprises, which were promulgated in the early years after the country started to implement the reform and opening policy.

The Law includes six chapters with a total of 42 articles, with unified provisions for the entry, promotion, protection, and regulating of foreign investment, the Law aims to improve the transparency of foreign investment policies and ensure that foreign-invested enterprises participate in market competition on a level playing field with predictable rules.

### I. What is the Foreign Investment Law

The Law will be the new fundamental law in the foreign investment fields, and as above mentioned, will replace the existing foreign investment laws. The existing foreign invested enterprises which are incorporated in accordance with the existing foreign investment laws may remain their enterprise organization in five years after the Law coming into force and then shall revise their chart documentation to conform with the Chinese Company Law.

### II. Definitions and Scope of Foreign Investment

According to the Law, foreign investment means foreign individuals, enterprises or other entities engaging in investment directly or indirectly within the territory of China<sup>1</sup>. Specifically, foreign investment shall include the following circumstances: (i) foreign investor establishes foreign invested enterprise in China itself or jointly with the other investors; (ii) foreign investor obtains shares, equity interests, assets or the other similar interests in an enterprise in China; (iii) foreign investor invests in new project in China itself or jointly with other investors; and (iv) other investment means as specified by the laws, administration regulations or regulations enacted by the State Council.<sup>2</sup>

### III. Investment Promotion

The Law sets up the principle of investment promotion from the following aspects:

1. Pre-Establishment National Treatment plus Negative List. After the Law's Effectiveness, the pre-establishment national treatment with a negative list (the "Negative List") is introduced nationwide in China. That is to say, the country will treat foreign investment no less favorably than domestic investment during the investment access stage, unless the Negative List provides otherwise. The Negative List was first introduced in 2014 in

<sup>1</sup> Article 2 of the Law.

<sup>2</sup> Article 2 of the Law

Shanghai Free Trade Zone to explore the further openness to foreign investments and was gradually introduced nationwide in 2016. The Negative List means only the investment areas and/or activities listed in the Negative List shall be reserved to Chinese nationals, and foreign investors are allowed to engage in investment activities in the areas outside of the Negative List equal footing with Chinese nationals. The current Negative List was jointly enacted by the National Development and Reform Commission and the Ministry of Commerce in 2018, there are 48 areas where foreign investment is restricted requiring pre-approval or forbidden or is banned. We noticed the recent news from the State Council that a new version Negative List is likely to be released in this 2019.

2. Fairness and Equality. The Law also underscores the fairness and equality from the following aspects: government policies supporting enterprise development shall apply equally to foreign invested enterprises ; foreign invested enterprises<sup>1</sup> will be able to participate into the standard formulating and the compulsory standard of the country shall applied to foreign invested enterprise equally<sup>2</sup> ; the foreign invested enterprises may participate in the governmental procurement on an equal footing;<sup>3</sup> foreign invested enterprise shall be allowed to raise funds by issuing securities or through other means like domestic enterprises.

3. Service-oriented Government. The Law states the government will develop a foreign investment service system to provide consultation and services for foreign investors and foreign invested enterprises with respect to laws and regulations, policy measures and investment project information.

#### IV. Investment Protection

Expropriation, capital remittance, intellectual property rights protection, forced technology transfer have long time been the major concerns of foreign investors and foreign invested enterprises, as these issues are close to the interests of foreign investors and foreign invested enterprises. Now, the Law addresses to such issues and highlights the protection of foreign investors' legitimate interest in China, including,

1. Governmental Expropriation and Compensation. The Law provides that, in general, foreign investors' investments are not subject to governmental expropriation. Only under special circumstances and for the public interest, the government may expropriate or requisition their investments, but must promptly provide fair and reasonable compensation

2. Capital Remittance. The Law states that capital contributions, profits, and returns on investment of foreign Investors may be freely transferred outside China in RMB or in foreign currency. The existing laws also specify that the foreign investors' legitimate income in China is allowed to be freely remitted outside China, however, in practice,

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<sup>3</sup> Article 9 of the Law

<sup>4</sup> Article 15 of the Law

<sup>5</sup> Article 16 of the Law

foreign investors may encounter delay. It remains to be observed the implementation of the Law after its effectiveness. It is notable that three days after the Law was passed, the State Administration for Foreign Exchange released a circular to relax and ease the rules regarding cross-border financing activities by multinational companies.

### 3. Intellectual Property Rights Protection and Banned Forced Technology Transfer.

China has been subject to criticism on intellectual property rights protection and forced technology transfer in relation to foreign investment. Now, the Law addresses to such criticism and provides that the State will protect the intellectual property rights of foreign investors and foreign invested enterprises in accordance with law and encourage technology cooperation based on voluntariness and commercial norms. The governmental agencies and officials shall not force technology transfer by administrative means. Similarly, three days after the Law was passed, the State Council enacted and implemented the Decision of the State Council to Amend and Repeal Certain Administrative Regulations (the "Decision"). The remarkable part of the Decision is the revision to the Chinese Technology Importation and Exportation Administrative Regulation (the "Technology Regulation") and removes Item 3 of Article 24, Article 27 and Article 29 of the Technology Regulation. The above articles of the Technology Regulation imposed heavy liabilities for warranty against defect on technology transferor, specified the technology improvement should belong to Chinese parties, and restricted the terms on the usage of transferee's technology. The removal of such stipulations shows China's determination and initiative on implementing the spirit of the Law and we believe this will enhance the confidence of foreign investors and foreign invested enterprises on the enhancing investment environment in China.

In addition, the Law also states the governmental agencies and officials shall keep trade secret of foreign investors and foreign invested enterprises and shall not divulge to and share with others illegally.

### 4. Government Performance

The Law provides that local governments shall not issue administrative documentation to restrict or impair the legitimate interests of foreign invested enterprises or increase the foreign invested enterprises burden<sup>1</sup> and local governments shall perform the contracts with foreign investors or foreign invested enterprises and keep the commitment to foreign investors or foreign invested enterprise as well<sup>2</sup>. Also, the Law states foreign invested enterprises may protect their legitimate interests via administrative complaint, administrative review and administrative litigation against government agencies and governmental officials<sup>3</sup>.

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6 Article 24 of the Law

7 Article 25 of the Law

8 Article 26 of the Law

## V. Regulating Investment

The Law states (i) foreign investors are prohibited from investing in prohibited industries on the Negative List, and shall comply with the specified requirements when investing in restricted industries <sup>1</sup>; (ii) if for the industries that foreign investors shall apply for licenses, the governmental agencies shall treat such application same as one by domestic investors <sup>2</sup>; (iii) foreign invested enterprises shall conform with the Chinese Company Law and Chinese Partnership Law in terms of their organizational forms, institutional frameworks and activities etc. in China <sup>3</sup>; (iv) foreign investors who merge with or acquire Chinese enterprises or otherwise participate in concentration of undertakings must submit to anti-monopoly review <sup>4</sup>; (v) foreign investors or foreign invested enterprise shall file information reports to the governmental agencies in charge <sup>5</sup>; (vi) if foreign investment affects or may affect national security, the State may launch state security review against such investment<sup>6</sup>

## Epilogue

In a nutshell, the Law releases the signal of greater transparency, and will boost Chinese markets appeal to foreign investment. As the Premier Li Keqiang mentioned, China's opening-up measures will not come on a one-time basis, instead, it is introduced quarter after quarter and year after year. In hindsight, when we review the course of China's opening-up we will recognized how much tremendous change it has brought to the country. However, as some comments noted the Law is lack of details and vague and it remains to be seen how the implementation regulations and rules will fill in the gap and we will keep a close eye on the progress of the release of implementation regulations.

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9 Article 28 of the Law

10 Article 30 of the Law

11 Article 31 of the Law

12 Article 33 of the Law

13 Article 34 of the Law

14 Article 35 of the Law .

## Patent Developments in the China Biotech/Pharma Sector

by Wang Ying, Partner - Anjie Law Firm

With a large number of overseas biomedical talents returned to China for development in the past decades, China's strong support for innovation in recent years, together with the introduction of a series of favorable policies by National Medical Products Administration (NMPA, former CFDA) since 2015, China has now become a hot land for global pharmaceutical research and development.

As a critical factor in fostering the pharma and biotech innovation, patent protection is closely related to the pharma company's business strategy and its corporate valuation. What new developments in pharmaceutical IP protection in China shall relevant companies, investors and IP practitioners pay attention to, and what are the main differences from biotech/pharma IP protection in Europe and the United States?

In this Whitepaper and companion Webinar, Ms. WANG Ying, a patent lawyer and partner of Anjie Law Firm will introduce (1) the outline of IP development in China, including the revised draft of the patent law and changes in IP litigation; (2) recent progress of China's patent linkage and data protection system; (3) introduction of typical litigation cases in the field of biomedicine, and (4) summarize the key issues and challenges that pharmaceutical company need to pay attention to.

### (1) The Outline Of IP Development In China

Since the Specialized IP courts established in Beijing, Shanghai and Guangzhou in 2014, tremendous changes have been taken place in the IP judicial system. For examples, technology investigation officers are now widely used in patent or trade secret litigation cases to help with the technical facts finding. Although China is not a common law country, China now emphasizes more on the use of "guiding cases" or "leading cases" to improve the consistency of judgments and to guide local court to deal with controversial issues.

On 1st of January 2019, IP tribunal of Supreme Court as the appellate IP court was launched to review the appeals from IP courts or other intermediate courts in those technology related cases, including patent, trade secret and anti-trust matters. So far, a judicial system consisting of nineteen IP tribunals of intermediate courts, three IP courts and one IP tribunal of Supreme Court as the appellate IP court was established to centralize the technology related litigation cases hoping to provide even more consistent judgements.

The other significant improvement in the past years is the increase of the damage in contrast to China being criticized for decades for its low damage regarding IP infringement issue. According to the latest draft of the Chinese Patent Law published for comments in January 2019, up to five times punitive damages for willful infringement was introduced, and the statutory damage was proposed to increase to 5 million RMB. It is believed the new amendment of Patent Law will be issued this year.

Chinese government has done all means to tackle the problem of IP infringement and

punishment on those who have serious mis-conducts in intellectual property such as repetitive infringement, refusing to implement effective decision and etc. In the Government work report made by Premier LI Keqiang during the 13th National People's Congress in March 2019, China will further strengthen IP protection and improve the system of punitive damages for IP infringement.

## **(2) Recent Progress Of China's Patent Linkage And Data Protection System**

With the reform in drugs and medical device review and approval system since 2015, lots of new policies and regulations have been introduced by NMPA, to solve the problem of backlog of drug review applications, to improve the quality of generic drug, to support innovation in drug and medical device industries, etc. One of the hot topics under discussion is the patent linkage and data protection system.

Patent linkage, data protection and patent term extension policies have been mentioned in a series of NMPA announcement and government opinions. For data protection, an Implementation Measures was issued for public comments in April 2018. Without doubt, patent linkage is a very comprehensive work which involves the coordination of NMPA, China National Intellectual Property Administration (CNIPA) and the court. Further, many other factors such as the social medical insurance system will also impact the effectiveness of patent linkage system.

Although the timeline for all such patent linkage related reforms is still uncertain, in the latest draft of the Chinese Patent Law published for comments in January 2019, patent term extension of up to five years for innovative pharmaceutical patents was proposed.

## **(3) Typical Litigation Cases In The Field Of Biomedicine**

CNIPA is quite strict in accepting supplementation of post-filing data, in evaluating inventive step and granting broad claim scope, etc. When evaluating the pharmaceutical related IP in China, the investors or pharma companies should adopt different standards taking into consideration of the development in the IP legislation and judicial activities. Three typical pharma cases will be introduced in this Whitepaper and companion Webinar.

The first case is about the amendment of Markush claim. The Supreme Court in its latest decision in 2018, reversed the Beijing High Court's judgement of allowing the patentee to delete some definitions of the groups in a Markush claim during the invalidation procedure, which supported the Patent Reexamination Board's (PRB) practice of rejecting amendments made to a Markush claim during an invalidation procedure. Such judgement implies, to make the patent more stable, when drafting or prosecuting the application, the applicant should add more dependent claims to cover any possibly valuable intermediate scopes based on the optimal compound.

The second case is about the scope of protein sequence. Biotech and Pharma companies were disappointed for a long time as CNIPA only allows pretty narrow claims scope for protecting new gene or protein. In this case, the Supreme Court supports the PRB's

decision of allowing protein sequence claims to be limited by species and 99% identity together with the functional limitation. Although such claim scope is still narrow, it is much better than the scope of one specific sequence.

The third case discuss the principle of accepting supplementation of post-filing data during prosecution, invalidation or administrative litigation proceedings. From the latest patent administrative litigation case regarding AstraZeneca patent (related to product “Ticagrelor”) decided by Beijing High Court in December 2018, the post-filing data to manifest the inventive step is still un-acceptable. CNIPA and courts adopt a quite stricter rule in accepting post-filing data than patent offices in the U.S., Europe and Japan.

So far, the PRB and courts have the similar attitude of not allowing the patentee to submit post-filing data to prove the merely alleged technical effect in the specification. The applicant pursuing global patent protection shall understand such differences in China and try to disclose the data in the application document in a sufficient way when filing the application.

This Whitepaper and companion Webinar will be helpful to pharmaceutical companies, especially those multinational pharmaceutical cyecompanies, investors and the IP practitioners.

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