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TRIPS-plus Rules in International Trade Agreements and Access to Medicines

CHINESE PERSPECTIVES AND PRACTICES

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ABSTRACT

China has introduced pharmaceutical-related TRIPS-plus rules into its domestic law through its accession to the World Trade Organization and Phase One Agreement with the United States, thus further enhancing China's protection of pharmaceutical intellectual property (IP) rights. As a developing country, the critical factors for China's introducing these high standards of pharmaceutical IP protection include: the promotion of innovation in the pharmaceutical industry, the development of generic pharmaceuticals, the accelerated introduction of innovative medicines into the domestic market, and external drivers from negotiating international economic and trade agreements. In practice, the TRIPS-plus rules have been a "double-edged sword" for China's access to medicines, which has both positive and negative effects. Therefore, to reduce the potential negative impact of the TRIPS-plus rules on access to medicines, China has responded by taking full advantage of the "flexibilities" reserved by the rules of international trade agreements, adding and improving legal provisions to prevent patent abuse, encouraging more patentees to voluntarily implement the patent opening licenses, improving the regulations of its compulsory licensing system for pharmaceuticals, and promoting domestic pharmaceutical pricing and procurement reform. Additionally, China's practical practices illustrate that the potential conflicts between the TRIPS-plus rules and access to medicines need to be resolved through coordination between the international IP regime and the global health governance

arena and it suggests that the design of IP rules for pharmaceuticals at the international level should be changed from avoiding "free-riding" to "returning" all consumers who share the innovation costs.

Key words: TRIPS-plus rules; Pharmaceuticals; Phase One Agreement; China

INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) concluded in the Uruguay Round of negotiations in 1994, sets out a number of substantive minimum standards for patent protection. The most important development has been the push for WTO members to establish patent protection system for pharmaceuticals. However, with the rapid development of technology, the TRIPS Agreement, once believed by many negotiators as a "ceiling" for pharmaceutical intellectual property (IP) protection, has become the "floor" (Sell 2011). Thus, the recent new generation of bilateral and multilateral trade and investment agreements, such as the Trans-Pacific Partnership (TPP), include provisions that progressively ratchet up intellectual property rights (IPRs) protection for pharmaceuticals.

These provisions contained in the free trade agreements (FTAs) that expand existing obligations under the TRIPS Agreement (such as patent term extensions) or restrict the use of safeguards or flexibilities (such as restrictions on parallel imports or compulsory licensing) are known as TRIPS-plus provisions (Correa 2017). In addition, TRIPS-plus rules also include provisions that introduce issues not addressed by the TRIPS agreement, such as data exclusivity for biological products as stipulated in the TPP (Correa 2017).

The potential impact of the TRIPS-plus rules has attracted the attention of the international community, particularly its impact on access to medicines. In 2016, the report *Promoting Innovation and Access to Health Technologies* submitted by the United Nations Secretary-General's High-Level Panel on Accessibility of Medicines pointed out:

> "A number of provisions found in bilateral and regional FTAs exceed the minimum standards for intellectual property protection and enforcement required by the TRIPS Agreement. These provisions may impede access to health technologies, including those requiring governments to ease standards of patentability, drug regulatory authorities to link marketing approval to the absence of any claimed patent and the requiring of test data exclusivity instead of test data protection, to list a few." (United Nations Secretary General 2016)

Health is impossible without access to pharmaceutical products, and universal health coverage is only able to be achieved when there is affordable access to safe, effective and quality medicines and health products (World Health Organization n.d.). Therefore, the protection of pharmaceutical IPRs is not only related to the interests of innovators, but also to public health. The sudden outbreak of COVID-19 in early 2020 is another reminder of the importance of public health issues and the need to strike the right balance between pharmaceutical IP protection and public health maintenance.

As a developing country, China has introduced some TRIPS-plus rules since its accession to the WTO in 2001. On January 15, 2020, China and the United States reached the Economic and Trade

Agreement between the Government of the People's Republic of China and the Government of the United States of America (known as the Phase One agreement), in which Chapter 1, "Intellectual Property" provides detailed provisions on the protection of IPRs for pharmaceuticals. In accordance with the agreement, China will comprehensively strengthen the protection of IPRs of pharmaceuticals. Additionally, since this year, the Chinese government has indicated that it "will favorably consider joining the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)" (Jinping 2020), which illustrates that China may continue to introduce more pharmaceutical-related TRIPS-plus rules in the future.

The purpose of this article is to examine the TRIPS-plus rules that China has introduced and to analyze the critical factors in promoting China's introduction of these high standards and their impacts on China's access to medicines. The paper attempts to interpret and analyze China's policy position in introducing these high standard IP rules for pharmaceuticals, with a view to providing a policy reference for other developing countries. The following section provides the TRIPS-plus rules currently introduced by China in bilateral and multilateral trade agreements. It will focus on data exclusivity, patent term extension and patent linkage provisions as they are significant relevant issues for access to medicines. The paper then analyzes the critical factors for China's introduction of these rules, presents the impact of China's introduction of these rules on access to medicines and states how China reduces the potential negative impact of TRIPS-plus rules. The final section concludes.

PHARMACEUTICAL-RELATED TRIPS-PLUS RULES IN CHINESE DOMESTIC LAW

Pharmaceutical-related IP has long been a key issue in the negotiation of international economic and trade agreements. As a newcomer, China introduced data exclusivity obligations when it joined the WTO in 2001. The Phase One agreement reached earlier in 2020 provides patent term extension and effective mechanisms for early resolution of patent disputes which is known as patent linkage. These provisions are closely related to the accessibility of medicines and go beyond the requirements of the TRIPS Agreement obligations.

Data Exclusivity

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine's safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant's marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to "conduct the costly clinical research and trials necessary to obtain marketing approval" (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018).

However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other

data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621).

Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V "Trade-Related Intellectual Property System" of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

After its accession to the WTO, China transformed the provisions of Article 39(3) of the TRIPS Agreement and paragraph 284 of the Report of the Working Party on the Accession of China into domestic law and implemented regulations and measures on protection of undisclosed test or other data. Article 35 of the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (2002) (State Council 2002)[1] and Article 20 of the Provisions for Drug Registration (2007) (China Food and Drug Administration 2007)[2] paraphrased the contents in the Report of the Working Party on the Accession of China. In 2019, the Regulations for the Implementation of the Drug Administration Law of China (State Council 2019) was issued, and Article 34 thereof retains provisions mentioned above.

In addition, the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging Innovation on Drugs and Medical Devices (General Office of the State Council 2017) was issued in October 2017 and set forth requirements for the further improvement and implementation of the drug test data protection system. It provides that"[t]he trial data and other data obtained alone but not disclosed yet by an applicant for registration of an innovative drug, a drug for treatment of rare diseases, a child drug, an innovative biological product for treatment, or a drug arising from a successful patent challenge, shall be protected in a given period" (General Office of the State Council 2017, 18). Furthermore, the Chinese National Medical Products Administration published a draft on Implementing Measures for Pharmaceutical Test Data Protection for public comments in April 2018, articles 5 and 6 of which stipulate the detailed regulations (National Medical Products Administration 2018).

[1] These regulations have been replaced by (State Council 2019).

[2] These provisions have been replaced by (State Administration for Market Regulation 2020)

Table 1: Implementing Measures for Pharmaceutical Test Data Protection (draft for comment)

Drugs	Protection Period
Innovative drugs	6 years from the date of marketing authorization in China
Innovative therapeutic biologics	12 years from the date of marketing authorization in China
Orphan drugs	6 years from the date of the first approval of the relevant indication in China
Pediatric drugs	6 years from the date of the first approval of the relevant indication in China

Patent Term Compensation System

The patent term compensation system refers to restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval and extends patent terms for pharmaceutical products (Correa 2017, 4). The purpose of the system is to encourage innovation in the pharmaceutical industry by compensating for the "unreasonable curtailment" of the patent term. During the TRIPS negotiations, the US and EU proposed longer patent terms for pharmaceuticals and the other parties rejected this proposal (Kilici 2014). There are no provisions related to extensions of patent terms in TRIPS. In accordance with the TRIPS Agreement, the minimum standard for the patent protection period is 20 years from the date of filing. Although this provision allows members to provide a longer patent protection period, TRIPS members are not obliged to offer longer terms of protection more than 20 years from the date of filing for any technical field.

In the Phase One agreement, article 1.12 stipulates the patent term compensation system, which provides that:

> "With respect to patents covering a new pharmaceutical product that is approved for marketing in China and methods of making or using a new pharmaceutical product that is approved for marketing in China, China, at the request of the patent owner, shall make available an adjustment of the patent term or the term of the patent rights of a patent covering a new product, its approved method of use, or a method of making the product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that product in China. Any such adjustment shall confer all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims of the product, its method of use, or its method of manufacture in the originally issued patent as applicable to the approved product and the approved method of use of the product." (U.S.-China 2020, 1.12.2(b))

Compared with the provisions in the TPP and CPTPP (CPTPP 2018, 18.48),[3] the above provisions are more stringent in that it not only clarifies that the scope of the drug patent term extension covers a new product, its approved method of use, or a method of making the product, but also specifies that "China may limit such adjustments to no more than five years and may limit the resulting effective patent term to no more than 14 years from the date of marketing approval in China."

[3] Notably, Article 18.48 (Patent Term Adjustment for Unreasonable Curtailment: all of this Article including footnotes 45 through 48) is among the suspended provisions in the CPTPP (CPTPP 2018, Annex, 7).

It is worth noting that, prior to the Phase One agreement, China had already begun piloting this system. Article 17 of the 2017 Opinions proposed to "conduct the pilot program of the patent term compensation system. Some new drugs shall be selected for the pilot program, and patent term compensation shall be made, taking into account the time when the marketing is delayed due to clinical trial, evaluation and approval." Furthermore, Article 43(2) of the Request for Public Comments on the Patent Law (Draft Amendment), which was published by the Standing Committee of the National People's Congress on January 4, 2019, also stipulated the patent term compensation system (Peng and Meuwissen 2020).[4]

On October 17, 2020, the Patent Law of the People's Republic of China (2020 Amendment) was promulgated, and stipulated that:

> "For the purpose of making up the time required for the assessment and approval of the marketing of a new drug, the patent administrative department of the State Council may, at the request of the patentee, provide a patent term extension for an invention patent relating to the new drug approved for marketing in China. The extension may not exceed five years, and the total effective term of the patent after the new drug is approved for marketing shall not exceed 14 years." (National People's Congress 2020, 42.3)

The above provision is consistent with that in the Phase One agreement. As the general provisions on patent, the 2020 Patent Law is over-principled. Consequently, after its issuance, the State Intellectual Property Office issued the Proposed Amendments to the Rules for the Implementation of the Patent Law (Draft for Comments) in December 2020, which includes a more detailed compensation system for the term of pharmaceutical patents (State Intellectual Property Office 2020, 85).

Patent Linkage

Patent linkage is a system that links drug marketing approval procedures with the patent status (Liu 2012). It is a particular TRIPS-plus provision and the TRIPS Agreement includes no requirement to provide such a system. Proponents of this system argue that the purpose is "the prevention of the infringement that may occur if generic versions of a patented product were approved for commercialization" (Correa 2015). Opponents of the system argue that even spurious patents may function as barriers to generic drug registration under the patent system (Kilici 2014). Therefore, it may unduly delay the marketing approval for generic drugs and limit states' actions aimed at progressively realizing the human right to health (Correa 2017).

Patent linkage is described in Article 1.11 of the Phase One agreement ("Effective Mechanism for Early Resolution of Patent Disputes"), which stipulates the scope of application of the drug patent linkage system from the two aspects of pharmaceutical product type and patent type. From the perspective of pharmaceutical product type, the patent linkage system is applicable to a pharmaceutical product seeking marketing approval that relies on evidence or information concerning the safety and efficacy of a product that was previously approved, commonly, the "generics". From the perspective of patent type, Article 1.11 is applicable to a "patent claiming an approved pharmaceutical product or its approved method of use". In terms of the specific content of the system, Article 1.11 stipulates the notification mechanism, the dispute resolution mechanism before the marketing of generics and the

[4] Article 43(2) of the Request for Public Comments on the Patent Law (Draft Amendment): "for the purposes of making up the time for the review and approval of the listing of an innovative drug, the State Council may decide to extend the duration of the innovative drug invention patent of which the listing in China and abroad at the same time is applied for, the duration may be extended for not more than five years, and the total effective duration of the patent after the listing of the innovative drug shall not exceed 14 years."

"lockout period" system. Provisions concerning the patent linkage system in the Phase One agreement are similar to Article 18.53(1) of the TPP (which was suspended under the CPTPP), but differ from that of Article 18.53(2) of the TPP, providing an alternative to a patent linkage system.

Prior to the Phase One agreement, China had no legislation related to a patent linkage system. However, Item 16 of the 2017 Opinions proposed to "explore and establish a drug patent linkage system" and set a framework for the drug patent linkage system, including the creation of a list of marketed drugs, patent claims and challenges, and a "lockout period," which are basically similar to the linkage system in US law (Fuen 2020). Moreover, the "Opinions on Strengthening Intellectual Property Protection" issued by the General Office of the CPC Central Committee and the General Office of the State Council in November 2019 proposed again to "explore and establish a drug patent linkage system".

The 2020 Patent Law lays out, for the first time in Chinese legislation, a drug patent linkage system, which provides that:

> "Where, in the process of assessment and approval for the marketing of a drug, any dispute arises between the applicant for the marketing of a drug and the relevant patentee or interested party over the patent right related to the drug of which an application for registration is filed, the relevant party may file a lawsuit with the people's court, requesting a judgment as to whether the relevant technical solution of the drug of which an application for registration is filed falls within the scope of protection of any other person's patent on a drug. The medical products administration of the State Council may, within the prescribed time limit, make a decision on whether to suspend the approval of marketing of the relevant drug according to the effective judgment of the people's court. The applicant for the marketing of a drug and the relevant patentee or interested party may also apply to the patent administrative department of the State Council for an administrative adjudication on any patent dispute related to the drug of which an application for registration is filed. The medical products administration of the State Council shall, in conjunction with the patent administrative department of the State Council, develop specific connecting measures for the resolution of patent disputes in the stages of approval of drug marketing and application for the marketing of a drug, report such measures to the State Council, and implement them upon consent of the State Council" (National People's Congress 2020, 76).

The patent linkage system has attracted considerable attention in the lawmaking process, and numerous comments have been put forward by various parties. For example, it has been suggested that part of the provisions of the patent linkage system is related to drug approval and thus should not be included in the Patent Law (Constitution and Laws Committee 2020). Finally, the legislature pointed out that "the Mechanism for Early Resolution of Drug Patent Disputes is a newly established mechanism concerning the balance of interests between patentee and generic applicant, which should be steadily promoted; while for legal issues involving patents, the Patent Law should stipulate corresponding principles to provide necessary legal ground, and the specific content may be detailed by the relevant competent departments and judicial organs in accordance with the law and constantly improved in practice" (Constitution and Laws Committee 2020).

In summary, China has introduced data exclusivity, a patent linkage system, and a patent term compensation system into its domestic law through its accession to the WTO and the Phase One Agreement. The following is a discussion of why China, as a developing country, has introduced these high standards of pharmaceutical IPRs.

CRITICAL FACTORS IN PROMOTING CHINA'S INTRODUCTION OF TRIPS-PLUS RULES

As discussed above, the conclusion of the Phase One Agreement leads China to transform pharmaceutical-related TRIPS-plus rules into its domestic law. However, it could be argued that the deeper reason was that the experience of 40 years of reform and opening up had shown that it was in China's long-term interests to gradually introduce and improve the IPRs system, to join and integrate into the world IP system and the world trading system, and to strengthen the enforcement and protection of IPRs (Yi 2019). The data illustrate that the IP system has greatly promoted China's technological progress. For instance, in 1995, China's research and development (R&D) expenditure was only 34.87 billion yuan, and the number of patent application grants was only 45,000. In 2018, China's R&D expenditures had already reached 1,965.70 billion yuan, and the number of patent application grants reached a record of 2.447 million. The number of R&D expenditures and patent applications is 18.9 times and 21.4 times that of 2001, respectively (Bing and Lingyun 2020). In this context, it can be argued that the following factors have driven China to introduce higher standards of IP protection for pharmaceuticals.

The first critical factor was to spur innovation in drug manufacturing. In recent years, with the implementation of the "innovation-driven" national strategy and the reform of the drug review and approval system, the environment for new drug R&D has been greatly optimized in China, and enterprises have deployed in new drug R&D fields. As the R&D of new drugs is characterized by large investment, long cycle and high risk, some enterprises have called for strengthening the protection of IPRs to obtain sufficient profit return. For example, some National People's Congress delegates from Chinese pharmaceutical enterprises have suggested further protection of undisclosed test or other data for traditional Chinese medicine and biopharmaceuticals (Yan 2017, Ding 2020).

The second critical factor was to promote the development of generic pharmaceuticals. China is a leading country in the use of generic medicines. According to the statistics, more than 90 percent of China's 4000 pharmaceutical companies are generic medicine manufacturers, and the market size of generic drugs accounts for about 95 percent of chemical medicines (Institute of Pharmaceutical Sciences, et al. 2016). However, at present, China has both an overcapacity and a shortage of generics. On the one hand, a large number of pharmaceutical companies are concentrated in the low-cost generic drug market with low R&D and low capital access barriers. On the other hand, domestic generic drug companies have insufficient generic capacity (Haoran 2019). Hence, the 2017 Opinions emphasized the need to promote production of generic drugs, which stated that "adherence shall be given to encouraging innovation and promoting production of generic drugs as well as reducing drug expenses, and a list of drugs in which the patent right has expired, terminated or been voided and of which the generic production has not been applied for, shall be regularly published so as to guide the research, development and production of generic drugs and improve public availability of drugs."[5]

The third critical factor is to speed up the imports of innovative drugs to the Chinese market. According to statistics, from 2001 to 2016, 433 innovative medicines were approved for marketing in the United States, but only 133 were marketed in China. A number of new medicines marketed in China are on average 7 years later than those in Europe, Japan or the United States (China Pharmaceutical Enterprises Assoc. (CPEA), et al. 2016). In order to provide patients with timely access to effective medicines and encourage the imports of innovative drugs, China took the initiative to introduce patent term extension prior to the Phase One Agreement, which was proposed at the April 2018 State Council executive meeting, "providing patent protection period compensation of up to 5 years to the

[5] Item 19 of the 2017 Opinions.

new drugs that are simultaneously applied for marketing approval in China and abroad" (General Office of the State Council 2018).

The last critical factor is external driving force. Since the reform and opening up, the external impetus has been an important driving force for the construction and improvement of China's IP system. Obviously, the evolution of China's IP protection system for pharmaceuticals over the past 40 years of reform and opening up has been a result of interaction between China and the US (Yi 2019). As early as 1979, when diplomatic relations between the United States and China were established, the US-China Bilateral Trade Agreement of 1979 incorporated broad IP provisions, with Article 6(3) stating: "[t]he Contracting Parties agree that they shall seek to ensure that patent and trademark protection granted to each other's legal or natural persons, in accordance with their respective laws and with due regard to international practice, shall be commensurate with such protection granted by the other Party to itself" (U.S.-China 1979).

In 1991, the United States listed China as a "key country" in the Special 301 Report and initiated an investigation into China in accordance with the procedures. It pointed out that China lacked patent protection for pharmaceuticals and agricultural chemicals, and that counterfeit and generic medicines were rampant in the market (Yi 2019). After several rounds of consultations, both parties signed a Memorandum of Understanding on the Protection of Intellectual Property Rights Between China and the US (MOU) on January 17, 1992 (U.S.-China 1992). Because of which, China amended the Patent Law, expanded the scope of objects of patent protection (excluding food, beverages and condiments from the list of unauthorized objects, as well as pharmaceuticals and chemically-obtained substances), and extended the term of patent protection (from 15 to 20 years for inventions). China also issued the Regulations on Administrative Protection of Medicines in December 1992 to provide additional protection for the medicines covered by the MOU (U.S.-China 1992). During the WTO negotiations, the US made IPR protection a precondition for China's accession to the WTO in order to force China to comply with U.S. demands to resolve bilateral IPR issues (Feng 2010). As noted earlier, China waived the flexibilities afforded to developing countries under the TRIPS and introduced TRIPS-plus rules for undisclosed test or other data protection for pharmaceuticals. The background for China's recent introduction of the pharmaceutical patent term extension and the patent linkage system is the well-known US-China trade war since 2018.

To sum up, China's introduction of the TRIPS-plus rules is the result of various factors. Since the reform and opening up, with the improvement of China's IPR legal system, the protection of IPRs as private rights have been widely recognized in China. There is no conceptual obstacle to pushing up the rules of IPR protection for pharmaceuticals in China, as the IP system has driven China's technological advancement and thus is linked to innovation. At the same time, the recent increase in the innovation capacity of some Chinese domestic pharmaceutical companies has created a demand for greater IPR protection. Despite these factors, the tension between pharmaceutical IPR protection and public health makes the introduction of some high-standard IP rules in China controversial. Therefore, the double-edged nature of the TRIPS-plus rules makes the timing of introducing these regimes extremely important (He and Lu 2009). Some scholars have argued that the timing may depend on two factors: "first, after the substantial development of the branded medicine industry, China needs to expand internationally and legally to ensure a return on investment for its innovations. The second is that the system can be introduced as a compromise arrangement for different industries when facing the pressure of trade negotiations from the US and Europe" (Liang 2019). From the foregoing analysis, the current state of development of China's pharmaceutical industry and the trade war between China and the United States have contributed to the emergence of the timing.

THE IMPACTS OF TRIPS-PLUS RULES ON ACCESS TO MEDICINES IN CHINA

The pharmaceutical industry is a special industry, involving not only the interests of original drug enterprises and generic drug enterprises but also the life and health of people. The protection of IPRs for drugs is closely intertwined with the prices and availability of those drugs. Generally speaking, generic drugs will be launched after expiration of the patent of original drugs, resulting in a "plunge" of drug prices which is generally referred to as the "patent cliff" in pharmaceutical prices (Fuen 2020). This occurs so long as the generic medicines have the same active ingredients, dosage, route of administration and intended use.

From foreign practice and experience, drug patent linkage, patent term extension and data exclusivity will directly or indirectly extend the duration of market exclusivity of branded drugs and postpone the marketing of generic drugs and the appearance of a "patent cliff" of drug prices, thus affecting the availability of drugs (Fuen 2020). For instance, originator drug enterprises have greatly extended the duration of market exclusivity through "evergreening of patents", such as patents on a drug's approved method of use, or method of making the product with a combination of a "lockout period" in the pharmaceutical patent linkage system.

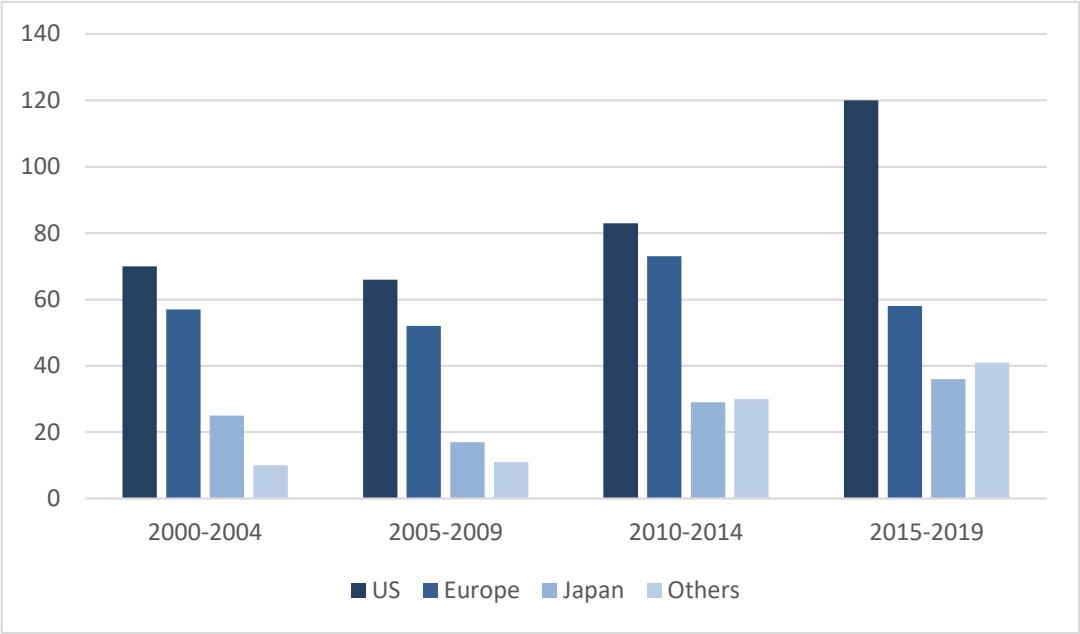
Currently, China has merely introduced patent linkage and patent term compensation systems for pharmaceuticals in 2020, and the relevant provisions will not come into effect until 2021, so it is impossible to assess the impact of these systems at this time. However, China introduced data exclusivity for pharmaceuticals upon its accession to the WTO, and it has implemented this system for nearly two decades. The following is an analysis of the impact of data exclusivity on drug accessibility. Since China's accession to the WTO, the provision of six years of exclusive protection for unclosed test or other data has brought the following two contradictory impacts.

On the one hand, data exclusivity has a significant negative impact on the accessibility of medicines. It is mainly reflected in the following two aspects:

First, data exclusivity has not played the role of "incentive innovation". After more than a decade of practice since the introduction of data exclusivity in China, China's pharmaceutical industry has not significantly improved its innovation capacity and is still challenged by the "gap between the quality of marketed products and the international advanced level". According to the statistics, during 2000-2004, pharmaceutical companies outside the United States, Europe, and Japan marketed 10 innovative drugs, accounting for only six percent of the global market. In contrast, from 2015 to 2019, pharmaceutical companies outside the United States, Europe, and Japan launched 41 innovative drugs, accounting for only 16 percent of the global market. The share of innovative drugs marketed by pharmaceutical companies outside the United States, Europe, and Japan increased by only 10 percent (see Figure 1) (European Federation of Pharmaceutical Industries and Associations 2020).

Secondly, data exclusivity is a policy factor that delays the marketing of generic drugs in China thereby affecting access to medicines. For example, the hepatitis C medicine Sovaldi produced by Gilead is priced about $1,000 a tablet in the US while it costs about $10 for a generic one in India (Sun 2015). The main reason India is able to manufacture a generic version of Sovaldi is that the Indian Patent Office refuses to grant patent rights, including patents of pro-drug and base chemical compounds, for Sovaldi (Na and Jing 2014). After that, Gilead signed a non-exclusive license agreement with Indian generic medicine manufacturers. According to the agreement, Indian pharmaceutical manufacturers obtain the complete technology transfer from Gilead to produce Sovaldi and fix their own prices (Sun 2015). The patent application of Sovaldi in China has also been rejected. However, although not granted a patent, according to the current provisions on the exclusive right of protection for undisclosed test or other data in China, it will still be protected for 6 years after it

Figure 1. Number of New Chemical and Biological Entities (2000-2019)



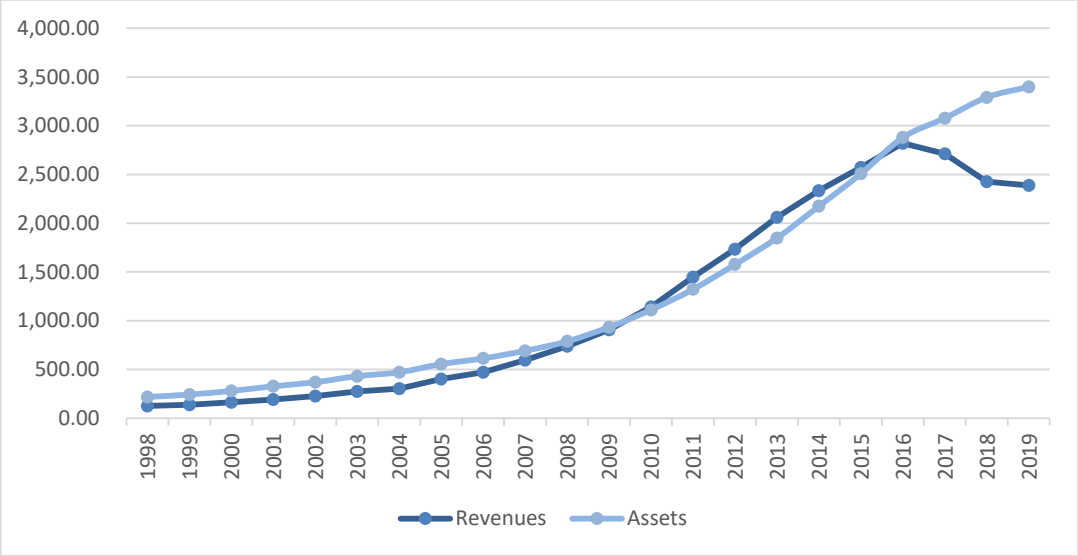
Source: SCRIP – EFPIA calculations (according to nationality of the mother company).

is approved for listing. During this period, a generic version produced by Chinese pharmaceutical enterprises is unable to be sold on the market. Hence, China's protection on undisclosed test or other data for a period of six years delayed the entry of generic drugs into the market, which inevitably led to exorbitant prices and limited patient access to medicines in China.

On the other hand, however, data exclusivity has also had a positive impact on the level of accessibility of medicines in China. This is mainly reflected in the rapid development of China's pharmaceutical industry since its accession to the WTO. For instance, in 2001, China's pharmaceutical and medicine manufacturing industry assets were 328.11 billion yuan and the amount of revenue was 192.44 billion yuan. In 2019, China's assets reached 3398.15 billion yuan and the amount of revenue reached 2388.42 billion yuan. The amount of assets and revenue is 10.35 times and 12.41 times that of 2001 (see Figure 2). From an economic point of view, the increased level of IPR protection in China plays a role in promoting trade and attracting foreign investment. For example, the evidence suggests that US-headquartered multi-national enterprises (MNEs) are sensitive to improvements in IPRs in developing countries in making foreign location decisions (Chow and Lee 2018). Thus, we could argue that the overall rapid development of China's pharmaceutical industry has played a positive role in improving access to medicines in China. This has also been confirmed by relevant research. Some scholars have used the data on 24 provinces/cities to analyze the current situation of the accessibility of low-cost drugs in terms of the overall situation, accessibility, and affordability, and concluded that the accessibility of low-cost drugs is very high. In terms of accessibility, only some of the low-priced drugs are out of supply and in short supply for a short period of time, in a small range and intermittently in some provinces, regions and medical institutions, but not for a long period of time in a large range. In terms of affordability, although the prices of low-priced drugs have generally increased after the implementation of the low-priced drug policy, they are still affordable (DU, et al. 2018).

Additionally, with respect to drug accessibility, the main problems facing China at present are the inability of innovative drugs to meet market demand and the delay and low quantity of foreign

Figure 2. Assets and Revenues of Pharmaceutical Manufacturing in China, 2001-2019 (billion CNY)



Source: Wind Economic Database.

innovative drugs on the market. Therefore, some scholars believe that to solve the problem of drug accessibility in China, it is fundamentally necessary to strengthen the R&D and generic capacity of the domestic drug industry (Haoran 2019).

Ultimately, from China's practice, the impact of pharmaceutical-related TRIPS-plus rules on the accessibility of medicines in China is double-edged, with positive facilitators and negative impediments. This uncertainty also illustrates that the high standards of IP rules for pharmaceuticals are closely related to the soil on which they are based, i.e., the conditions of each country, and that the system itself is neutral if the original rule designer's intentions are not considered.

CHINA'S PRACTICES TO REDUCE THE POTENTIAL NEGATIVE IMPACT OF TRIPS-PLUS RULES ON ACCESS TO MEDICINES

Although China had considered introducing pharmaceutical-related TRIPS-plus rules prior to the Phase One Agreement, there were differences in content from the Phase One Agreement. Furthermore, the Phase One Agreement provides detailed regulations on the patent term extension and patent linkage system. These systems may extend the monopolization period of the original drug and affect access to medicines. Hence, China has taken the following countermeasures to balance the tension between high standards of IPR protection rules and public health.

First, China has taken full advantage of the flexibility of the Phase One Agreement to design related systems to avoid abuse of the system. For instance, in terms of patent term extension in the Phase One Agreement, the first two paragraphs of Article 1.12 provide for a patent term extension system, and the third paragraph provides that "The United States affirms that existing US measures afford treatment equivalent to that provided for in this Article." Hence, when China transforms the provisions of the Phase One Agreement into domestic law, it is necessary to confirm the specific provisions of the existing US measures. Under the Phase One Agreement, the patent term extension

system to be established by China shall at least be applicable to "a patent covering a new product, its approved method of use, or a method of making the product." However, the extension of the patent term required under the Phase One Agreement provides no limitations that can be found under US law where the extension to compensate for delays in the marketing approval procedures applies to only one patent per product (35 U.S. Code § 156 n.d.). Consequently, China faces a number of such problems in transforming the new pharmaceutical patent protection system into domestic law.

Second, China has added provisions with respect to the abuse of patent rights and patent open license in the 2020 Patent Law. Article 20 of the 2020 Patent Law provides that: "Patent applications and the exercise of patent rights shall adhere to the principle of good faith. Patent rights shall not be abused to damage the public interest or the lawful rights and interests of any other person. Any abuse of patent rights to preclude or restrict competition, which constitutes a monopolistic act, shall be handled in accordance with the Anti-monopoly Law of the People's Republic of China." Competition laws and policies are considered to be able to effectively prevent anti-competitive behaviors such as price collusion, unreasonable restrictions on new technologies, and hindering companies of generics from entering the market, which lead to rising drug prices (Haoran 2019). Currently, China's regulation of pharmaceutical monopoly is still in its infancy, and the provisions in the Anti-monopoly Law of the People's Republic of China are not detailed. Therefore, some scholars suggest that drug price monopoly should be taken as the key for identifying the role of the government and the market to improve the operational framework for regulating pharmaceutical monopoly and maintaining the healthy and stable development of the pharmaceutical industry (Jing 2018). Additionally, in order to promote the exploitation and application of patents, Articles 48-52 concerning the open license system are added in the 2020 Patent Law. Article 50 provides that: "Where a patentee voluntarily files a written declaration with the patent administrative department of the State Council, indicating its willingness to permit any entity or individual to exploit its patent and specifying the royalty payment methods and rates, the patent administrative department of the State Council shall make an announcement and implement an open license." In order to encourage more patentees to voluntarily implement the patent opening license, Paragraph 2 of Article 51 further provides that: "During the period of implementation of the open license, the patent annuity paid by the patentee shall be reduced or waived accordingly." Whether these newly added provisions will have a positive impact on drug accessibility remains to be proved in practice.

Third, China has improved the regulations of a compulsory license system for pharmaceuticals. As early as 1984, China enacted the Patent Law which provided provisions on compulsory licensing, and which has been constantly amended and improved in 1992, 2000 and 2008 Patent Law amendments. In 2012, the China National Intellectual Property Administration issued the revised Measures on Compulsory Patent Licensing to provide detailed provisions on the conditions and procedures for application of various compulsory licensing.

From foreign practice, in terms of solutions to domestic public health, the most significant and operable compulsory licensing is the compulsory licensing under national emergencies or abnormal circumstances or for the public interest. Therefore, the Opinions on Reform and Improvement of Policies on Guarantee of Supply and Use of Generic Drugs (the 2018 Opinions) was issued in 2018, which first defines the "abnormal circumstances which threaten the public sanitary and health security" as "national emergencies or abnormal circumstances or for the public interest" (General Office of the State Council 2018). It also provides that the causes of such circumstances included not only an outbreak of major and serious infectious diseases or other abrupt public health events, but also the shortage of drugs for the prevention or treatment of major and serious diseases. "Major and serious diseases" include not only infectious diseases, but also other non-infectious diseases such as cancer. In addition, on the basis of Article 6 of the Measures on Compulsory Patent Licensing, the 2018 Opinions further clarified that the competent departments of the State Council for implementation

of compulsory licensing shall be National Health Commission which works together with the Ministry of Industry and Information Technology and National Medical Products Administration.

After the signing of the Phase One Agreement, some scholars argued that the patent linkage system and drug data protection may pose obstacles to the implementation of the compulsory patent license, affecting the timely resolution of the public health crisis, and suggested to further improve the compulsory license system for pharmaceutical patents, to build an effective link between the pharmaceutical patent linkage system and patent compulsory license system, and to provide limits and exceptions to the drug data protection (Fuen 2020).

Last, China has launched drug pricing and procurement reform. In recent years, China has undertaken reforms around drug prices in order to meet the needs of patients. For instance, the National Healthcare Security Administration (NHSA), established in 2018, will supervise health insurance across both urban and rural populations. The NHSA releases the work plan for the adjustment of the National Reimbursement Drug List (NRDL) each year. Innovative drugs and urgently needed imported drugs with higher prices will be included through negotiations. In 2019, for example, of the 97 drugs successfully negotiated, 70 new drugs had price reductions by an average of 60.7 per cent (news.china.com 2019). The aforementioned Gilead's Sovaldi, was approved for marketing in China in 2017, priced at 23,000 RMB. In 2019, through NHSA's negotiations, Sovaldi was included in the NRDL and the price was reduced 4,368 yuan, a reduction of 81 percent (Gilead 2017).

Meanwhile, China removed import tariffs on cancer drugs on May 1, 2018 and lowered the value added tax (VAT) on May 3, 2018 (General Office of the State Council 2018). Furthermore, China released the National Pilot Plan of Centralized Drug Procurement in 2019 and launched a new round of drug pricing and procurement reform. The reform was coined the "4+7" procurement reform, which implemented in 4 municipalities (Beijing, Shanghai, Tianjin and Chongqing) and 7 cities (Guangzhou, Shenzhen, Xi'an, Dalian, Chengdu, Xiamen). One of the purposes of the reform is to significantly lower drug prices and reduce the patients' burden of drug costs.

CONCLUSIONS

To conclude, China has introduced pharmaceutical-related TRIPS-plus rules into its domestic law through its accession to the WTO and Phase One Agreement, thus further enhancing China's protection of pharmaceutical IPRs. As a developing country, the critical factors for China's introducing these high standards of IPR protection for pharmaceuticals include the promotion of innovation in the pharmaceutical industry, the development of generic pharmaceuticals, the accelerated introduction of innovative medicines, and external drivers from negotiating international trade agreements. In China's practice, the pharmaceutical TRIPS-plus rules have been a "double-edged sword" for China's access to medicines, which has both positive and negative effects. Therefore, while China has further introduced high standard IPR rules for pharmaceuticals, it has also responded by taking full advantage of the "flexibilities" reserved by the rules of international trade agreements, adding and improving legal provisions to prevent patent abuse, encouraging more patentees to voluntarily implement the patent opening license, improving the regulations of compulsory license system for pharmaceuticals, and promoting domestic pharmaceutical pricing and procurement reform, in order to reduce the potential negative impact of TRIPS-plus rules on access to medicines in China.

Moreover, from China's practices, the TRIPS-plus rules have been introduced primarily through participation in international economic and trade agreement negotiations, and access to medicines is a common challenge facing both developing and developed countries, thus potential conflicts between the TRIPS-plus rules and access to medicines need to be resolved through coordination between the international IP regime and the global health governance arena. As more and more

countries increase the level of protection of IPRs for pharmaceuticals, multi-national pharmaceutical enterprises are able to utilize the high standard of IP rules as important instruments for the global sharing of innovation costs, the prices of drugs "skyrocketed" with higher rules on protection of IPRs, the global poor, who cannot afford the burden of medical charge, are suffering actual losses of benefit. Therefore, it could be argued that the design of IP rules for pharmaceuticals at the international level should be changed from avoiding "free-riding" to "returning" to all consumers who share the innovation costs. Furthermore, the COVID-19 pandemic is a reminder that we should start working in this direction as early as possible.

BIBLIOGRAPHY

n.d. "35 US Code § 156." *Extension of Patent Term.*

Bing, Han, and Gao Lingyun. 2020. "Opening Its Doors to Foreign Investment: The Evolution of Trade-Related Investment Measures and their Economic Impacts in China." *South-South Integration and the SDGs: Enhancing Structural Transformation in Key Partner Countries of the Belt & Road Initiative, UNCTAD/BRI Project/RP4.* Beijing: UNCTAD, July.

China Food and Drug Administration. 2007. "Provisions for Drug Registration (Decree No. 28)." July 10. Accessed March 2021. https://www.pkulaw.com/en_law/30e346b2cd4c19b1bdfb.html.

China Pharmaceutical Enterprises Assoc. (CPEA), China Pharmaceutical Industry Assoc. (CPIA), Medicines & Health Products China CoC for Import and Export, and R&D-based Pharmaceutical Assoc. Commitee (RDPAC). 2016. "Fostering a Sustainable Ecosystem for Drug Innovation in China." *RDPAC.org.* October. Accessed March 2021. http://enadmin.rdpac.org/upload/upload_file/1577873373.pdf.

Chow, Daniel C.K., and Edward Lee. 2018. *International Intellectual Property: Problems, Cases and Materials (3d edition).* West Academic Publishing.

Constitution and Laws Committee, National People's Congress. 2020. "Report of the results of the review with respect to the Draft Amendment to the Patent Law of the People's Republic of China." October 19. Accessed March 2021. http://www.npc.gov.cn/npc/c30834/202010/d43160bfb7a04a98a4058d2ce46053dd.shtml.

Correa, Carlos. 2015. "Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for Access to Affordable Medicines." *South Centre Working Papers #62.* September. Accessed March 2021. https://www.southcentre.int/wp-content/uploads/2015/08/RP62_IP-in-TPP-Increasing-the-Barriers-Access-to-Affordable-Medicines_EN.pdf.

Correa, Carlos. 2017. *Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements.* Research Paper 74, South Centre.

CPTPP. 2018. "Comprehensive and Progressive Agreement for Trans-Pacific Partnership Preamble." Accessed March 2021. https://www.mfat.govt.nz/assets/Trade-agreements/CPTPP/Comprehensive-and-Progressive-Agreement-for-Trans-Pacific-Partnership-CPTPP-English.pdf.

—. 2018. "Comprehensive and Progressive Trans Pacific Partnership: Chapter 18 Intellectual Property." *Comprehensive and Progressive Agreement for Trans-Pacific Partnership texts and resources.* Accessed March 2021. https://www.mfat.govt.nz/assets/Trade-agreements/TPP/Text-ENGLISH/18.-Intellectual-Property-Chapter.pdf.

Ding, Lieming. 2020. "Incentivizing Drug Innovation and Speeding up the Implementation of Drug Trial Data Protection System." *National People's Congress (www.ceweekly.cn).* May 24. Accessed March 2021. http://www.ceweekly.cn/2020/0524/298914.shtml.

DU, Wen-wen, Wei XU, Gong-jie CAI, and li MA. 2018. "The analysis of low cost medicine's accessibility in China: Based on the empirical study from 24 provinces and cities." *Chinese Journal of Health Policy* 11:3, 72-77.

European Federation of Pharmaceutical Industries and Associations. 2020. "The Pharmaceutical Industry in Figures 2020." *efpia.eu.* Accessed March 2021. https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf.

Feng, Jiehan. 2010. "Protection and Limitation of Pharmaceutical Laboratory Data Under the TRIPS Agreement." *Wuhan University International Law Review* 1:125-144.

Fuen, Qui. 2020. "Public Health under the Intellectual Property Terms of the China-US Economic and Trade Agreement: Conflicts and Solution." *Electronic Intellectual Property* 3:4-13.

General Office of the State Council. 2018. "Executive Meeting of the State Council." April 13. Accessed August 2020. http://www.gov.cn/xinwen/2018-04/13/content_5282188.htm.

—. 2018. "Premier Li Keqiang presided over a State Council executive meeting to determing the development of "Internet and healthcare" measures." *www.gov.cn.* April 12. Accessed March 2021. http://www.gov.cn/premier/2018-04/12/content_5282000.htm.

—. 2017. "The General Office of the CPC Central Committee and the General Office of the State Council on Issuing the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices." October. Accessed March 2021. https://www.pkulaw.com/en_law/41571a861f5d1c80bdfb.html.

—. 2018. "The Opinions on Reform and Improvement of Policies on Guarantee of Supply and Use of Generic Drugs issued by the General Office of the State Council." *pkulaw.com.* March 21. Accessed March 2021. https://www.pkulaw.com/en_law/d8cca6f47f410d15bdfb.html.

Gilead. 2017. "China Food and Drug Administration Approves Gilead's Sovaldi (Sofosbuvir) for Treatment of Chronic Hepatitis C. Virus Infectio." *Gilead News and Press, Press Release.* September 25. Accessed August 2020. https://www.gilead.com/news-and-press/press-room/press-releases/2017/9/china-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-treatment-of-chronic-hepatitis-c-virus-infection.

Haoran, Zhang. 2019. "Succession and Adaptaion of China's Pharmaceutical Patent Linkage Regime in a Competition Perspective." *Intellecutual Property* 4:51-70.

He, Lianhong, and Langlang Lu. 2009. "A Study on the Experimental Exception System for Pharmaceutical Invention Patents in China." *Present-Day Law Science* 6:67-76.

Institute of Pharmaceutical Sciences, Chinese Academy of Medical Sciences, China Pharmaceutical Ind. Information Center, and China Inst. of Food & Drug Testing & Cert. 2016. *Blue Book of Generic Drugs in China.* Beijing: Peking Union Medical College Press.

Jing, Chen. 2018. "Analysis of Drug Price Monopoly fom the Perspective of Anti-trust." *Journal of Heilongjiang University of Technology* 12:90-95.

Jinping, H.E. Xi. 2020. "Full Text of Chinese President Xi Jinping's Remarks at the 27th APEC Economic Leader's Meeting: Working Together for an Asia-Pacific Community with a Shared Future." *CPC Central Committee Bimonthly Qiushi.* November 20. Accessed March 2021. http://en.qstheory.cn/2020-11/23/c_565552.htm.

Kilici, Burcu. 2014. "Defending the Spirit of the Doha Declaration in Free Trade Agreements: The Trans-Pacific Partnership and Access to Affordable Medicines." *Loyola University Chicago International Law Review* 12:23-.

Liang, Zhiwen. 2019. "China's Path to a Pharmaceutical Patent Protection Period Compensation System: Improvement of the Draft Revised Patent Law (2019)." *Research on the Modernization of the Rule of Law* 4:127-139.

Liu, Benjamin P. 2012. "Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage." *Marshall Review of Intellectual Property Law* 11:623.

Na, Li, and Minghao Jing. 2014. "The Indian Gleevec Decision: A Path to Addressing Intellectual Property and Public Health Issues." *Hebei Jurisprudence* 12:19-25.

National Medical Products Administration. 2018. "Implementing Measures for Pharmaceutical Test Data Protection (draft)." April 26. Accessed March 2021. https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjyp/20180426171801468.html.

National People's Congress. 2020. "The Patent Law."

news.china.com. 2019. "70 New Drugs was included on the National Reimbursement Drug List." *news.china.com.* November 29. Accessed August 2020. http://news.china.com.cn/2019-11/29/content_75458557.htm.

Peng, Julia, and Stefaan Meuwissen. 2020. "China's New Amended Patent Law and Draft Implementation Rules - all that was expected and more to come." *JDSUPRA.* December 4. Accessed March 2021. https://www.jdsupra.com/legalnews/china-s-new-amended-patent-law-and-13108/.

Sell, Susan K. 2011. "TRIPS Was Never Enough." *Journal of Intellectual Property Law* 18:447-478.

Standing Committee of the National People's Congress. 2020. "Patent Law of the People's Republic of China (2020 Amendment) (Order No. 55)." October 17. Accessed March 2021. https://www.pkulaw.com/en_law/417f520f8bcb8de2bdfb.html.

State Administration for Market Regulation. 2020. "Measures for the Administration of Drug Registration (2020) (Order No. 27)." July 1. Accessed March 2021. https://www.pkulaw.com/en_law/340948.html?#0.

State Council. 2002. "Regulation for the Implementation of the Drug Administration Law of the People's Republic of China (Decree No. 360)." September 15. Accessed March 2021. https://www.pkulaw.com/en_law/bc45e945d98b089dbdfb.html.

—. 2019. "Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (2019 Amendment) (Order No. 709)." March 2. Accessed March 2021. https://www.pkulaw.com/en_law/bc45e945d98b089dbdfb.html.

State Intellectual Property Office. 2020. "Proposed Amendments to the Rules for the Implementation of the Patent Law (Draft for Comments)." November 30. Accessed March 2021. http://www.ccpit.org/Contents/Channel_3586/2020/1130/1311202/onlineeditimages/file71606701263218.pdf.

Sun, Amin. 2015. "An inaccessible life-saving drug: New hepatitis C drug won't make it to Chinese market." *finance.sina.com.cn.* July 6. Accessed September 19, 2020. http://finance.sina.com.cn/chanjing/gsnews/20150706/154122602330.shtml.

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US-China. 2020. "Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China (Phase One Agreement)." January 15. Accessed March 2021. https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf.

—. 1992. "Memorandum of Understanding on the Protection of Intellectual Property Rights Between China and the US." *pkulaw.com.* January 17. Accessed March 2021. https://www.pkulaw.com/eagn/100663487.html.

—. 1979. "The US-China Bilateral Trade Agreement of 1979." *pkulaw.com.* July 7. Accessed March 2021. https://www.pkulaw.com/eagn/100666275.html.

UNCTAD & ICTSD. 2013. *Resource Book on TRIPS and Development (Chinese Translation).* Beijing: Department of Treaty and Law, Ministry of Commerce, China Commerce and Trade Press.

United Nations Secretary General. 2016. "High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies." September 14. Accessed March 2021. http://www.unsgaccessmeds.org/final-report/.

World Health Organization. n.d. *Our Work: Access to Medicines and Health Products.* Accessed March 2021. https://www.who.int/our-work/access-to-medicines-and-health-products.

World Trade Organization. 2001. *Report of the Working Party on the Accession of China.* WT/MIN(1)/3, Geneva: WTO.

Yan, Xijuan. 2017. "China's pharmaceutical test data protection still lacks a legal basis." *National People's Congress (www.ce.cn).* March 5. Accessed March 2021. http://www.ce.cn/xwzx/gnsz/gdxw/201703/05/t20170305_20729942.shtml.

Yi, Jiming. 2019. "Sino-US Interactions and the Evolution of China's Intellectual Property System since the Introduction of Reform and Open Policy." *Jiangxi Social Sciences* 6:158-170.