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What Drug Companies Should Be Thinking About After the U.S.-China Trade Deal

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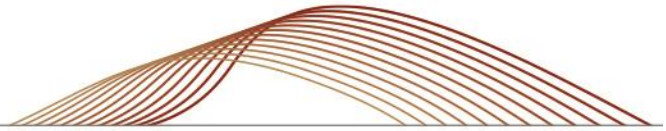
On January 15, 2020, the United States and China announced an economic and trade deal ("Phase One Trade Agreement") that could significantly improve the ability of U.S. and non-U.S. drug companies to protect their intellectual property rights and market their innovative pharmaceutical products in China. As part of the Phase One Trade Agreement, China has committed to providing a "patent linkage" mechanism (which echoes the Hatch-Waxman Act) for the early resolution of patent disputes before competitor drugs may be launched.[1] In addition, China has agreed to provide patent term extensions to compensate for "unreasonable delays" in patent grant and regulatory review periods.[2]

China's new commitments to the drug industry add, on an international level, to China's ongoing domestic structural reforms of its patent and pharmaceutical regulatory policy and law, and harness the administrative and judicial systems already in place to protect intellectual property and promote drug access in China. In this article, we begin by explaining the reforms that China has implemented at the domestic level over the past few years in connection with its growing pharmaceutical industry. We then turn to the key provisions of the Phase One Trade Agreement that are relevant for companies seeking to market their drug products in China, and how these provisions might be integrated into or dovetail with China's existing administrative, regulatory, and judicial framework. Finally, we offer some practical considerations for innovator drug companies in view of China's continuing reforms and obligations under the Phase One Trade Agreement.

I. The Phase One Trade Agreement Builds Upon Recent Reforms in the Chinese Pharmaceutical Industry

China is the second largest pharmaceutical market globally, with $137 billion in total sales in 2018.[3] Numerous global pharmaceutical companies saw accelerated growth in revenue in China in 2019.[4] In recent years, China has seen explosive growth in new drug development, ranging from innovative antibodies to new cell therapies.[5] Correspondingly, China has witnessed a record increase in the filing and approval of drug applications.[6] In 2018, for example, the Center for Drug Evaluation of the National Medical Products Administration of China received over 7,000 drug applications (including 457 investigational new drug applications, 157 new drug applications, and 123 biologics applications), and completed review of over 9,000 drug applications.[7]

China's recent domestic reforms to its pharmaceutical industry can be traced to 2015, when in an effort to stimulate innovation and improve patient access to existing drugs and new treatments, the



Chinese government initiated a series of regulatory reforms to expedite the review and approval of applications for drugs and medical devices:[8]

- First, the Chinese government proposed and began implementing a series of significant structural reforms for its pharmaceutical regulatory policy and law, including (1) accelerating the review and approval of drugs and medical devices; (2) creating an online database of approved drugs and drug patents; and (3) exploring potential clinical data protection and patent term extensions.[9]

- In 2017, the State Food and Drug Administration of China released draft policy guidelines exploring the creation of a "patent linkage" mechanism for the early resolution of pharmaceutical patent disputes.[10]

- On April 25, 2018, the Chinese government released draft regulatory guidelines for public comment on the implementation of drug test data protection, including data protections for new drugs (six years), new biologics (twelve years), orphan drugs (six years), drugs with pediatric indications (six years), and generic drugs with successful patent challenges.[11]

- On August 26, 2019, the Chinese government enacted the amended Drug Administration Law, with provisions directed to regulations that (1) support the development and marketing of drugs with pediatric indications, urgently needed drugs for life-threatening diseases, and orphan drugs; and (2) prohibit counterfeit medicines.[12]

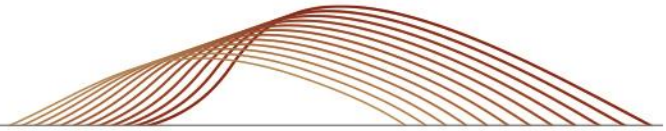
In tandem, ongoing efforts to reform China's patent judicial system and patent law have taken root. For example, on January 1, 2019, a specialized Intellectual Property Court of the Supreme People's Court of China was established to adjudicate appeals on patent and complex technical intellectual property cases nationwide.[13] Within a few days, on January 4, 2019, draft amendments to China's Patent Law, which contain provisions that provide patent term extensions to compensate for delays in regulatory review periods, were released for public comment.[14] And later that same year, on November 24, 2019, an official opinion from the Chinese government to enhance intellectual property protection, including establishing a patent linkage system for the early resolution of pharmaceutical patent disputes, was issued.[15]

II. Patent and Pharmaceutical Provisions of the Phase One Trade Agreement

Last week's Phase One Trade Agreement between the United States and China outlines China's commitments on the protection and enforcement of drug-related intellectual property rights, and will enter into force by February 14, 2020.[16] These commitments are generally consistent with China's ongoing broader structural reforms, discussed above, aiming to protect intellectual property and improve drug access.

Implementation and Timing

Within 30 working days after the Phase One Trade Agreement enters into force, China will release an Action Plan that includes the general measures to implement these commitments and the date by which each measure will go into effect.[17] While the precise path that China will take to effect these measures remains to be seen, China will likely release a combination of draft policy guidance, laws, and administrative and regulatory guidelines as part of the implementation process. China will also provide a public comment period of at least 45 days for all proposed implementation measures.[18]



Effective Mechanism for Early Resolution of Patent Disputes

Under the Phase One Trade Agreement, China has committed to establish a "patent linkage" mechanism for the early resolution of patent infringement disputes in connection with the marketing approval of a pharmaceutical product in China.[19] In establishing a patent linkage system, China has committed to provide (1) a system to provide notice to a patent holder, licensee, or holder of marketing approval if a third party drug applicant seeks to market a drug within the applicable drug patent term; (2) adequate time and opportunity for such a patent holder to seek remedies prior to marketing of an allegedly infringing product; and (3) procedures for administrative and judicial proceedings and expeditious remedies, such as preliminary injunctions.[20]

Both small molecule drugs and biologics are included in the patent linkage system of the Phase One Trade Agreement. At a high level, the Phase One Trade Agreement draws from the contours of the U.S. Hatch-Waxman framework for resolving patent disputes involving small molecule drugs, and provides a mechanism for litigating infringement disputes over drug product and method of use patents.[21] The mechanism under the Phase One Trade Agreement, however, does not expressly provide for the resolution of infringement disputes over manufacturing patents, which can be a key aspect of U.S. biosimilar cases under the Biologics Price Competition and Innovation Act (BPCIA).

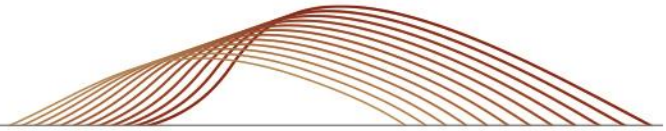
The Phase One Trade Agreement does not provide further details on the patent linkage system. For example, the Agreement does not specify the procedure for the patent notification process, the mechanism of filing suit, or the length of the stay of marketing approval for drugs. Instead, the Agreement provides broad parameters for the new system's foundation. As discussed above, under the Phase One Trade Agreement, China will release an Action Plan containing proposed measures that will likely provide more specific details about implementation of the patent linkage system.[22]

As China begins to formulate a concrete plan, the U.S. Hatch-Waxman system—and its over three decades of related jurisprudence—can provide helpful guidance. In addition, China's own domestic reform efforts to date may suggest the direction its patent linkage system will ultimately take. For example, and as discussed above, the State Food and Drug Administration of China released draft policy guidelines in 2017 exploring a potential patent linkage system.[23] These guidelines proposed that drug applicants seeking patent challenges shall provide notice within 20 days of the drug application filing, branded drug companies shall file suit within 20 days of the receipt of the notification, and the length of the litigation stay would be up to 24 months.[24]

Finally, the Phase One Trade Agreement also does not include any details regarding the submission and maintenance of a patent list that would be analogous to the U.S. FDA's Orange Book. But as discussed above, the National Medical Products Administration of China has issued relevant guidance and has already implemented reforms to build an online database of patents covering drug products.

Patent Term Extension

Under the Phase One Trade Agreement, China has committed to provide patent term extensions to compensate for "unreasonable delays" that occur in granting the patent or during pharmaceutical product marketing approvals.[25] With respect to the granting of a patent, an unreasonable delay includes a delay in the issuance of a patent of more than four years from the date of filing, or three years after a request for examination of the application, whichever is later.[26] Otherwise, the term "unreasonable delay" is not defined.



With respect to delays during regulatory review, pending legislative reform on the Chinese patent law may provide guidance on what may be considered "unreasonable." The draft Amended Chinese Patent Law, released on January 4, 2019 and discussed above, includes provisions on patent term extensions similar to existing U.S. law. Specifically, a Chinese drug patent term may be extended for up to five years to compensate for delays during regulatory review, provided that the resulting effective patent term is no more than fourteen years from the marketing of the new drug in China.[27]

Consideration of Supplemental Data

Under the Phase One Trade Agreement, China has agreed to permit drug patent applicants to rely on supplemental data to satisfy relevant requirements for patentability during patent examination proceedings, patent review proceedings, and judicial proceedings.[28] In the U.S., post-filing supplemental experimental data, such as data showing unexpected results, utility of an invention, and distinctions between an invention and the prior art, are often submitted during patent prosecution, post-grant patent office proceedings, and litigation in support of the patentability of pharmaceutical inventions.

We note that, before 2017, Chinese patent applicants and patentees were generally not permitted to rely on post-filing experimental data during prosecution or post-grant proceedings.[29] To address this issue, the 2017 revisions to the Chinese Patent Examination Guidelines and the 2018 draft guidelines issued by the Supreme People's Court of China require examiners and courts to consider post-filing experimental data submitted to satisfy certain patentability requirements.[30] These changed patent examination and judicial guidelines are consistent with China's commitments under the Phase One Trade Agreement.

Counterfeit Medicines

Under the Phase One Trade Agreement, China has committed to take enforcement action against counterfeit pharmaceutical and related products, including active pharmaceutical ingredients and biological substances, and share with the U.S. the registration information of properly-inspected pharmaceutical raw material sites.[31] China has also committed to begin publishing online data on enforcement measures.[32] These commitments are consistent with the prohibition of counterfeit medicines under the Amended Chinese Drug Administration Law, which was enacted in 2019.[33]

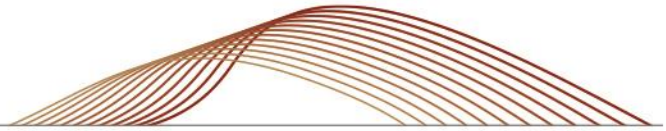
No Provisions on Data Exclusivity

We note that, while the preamble of Chapter One, Section C of the Phase One Trade Agreement acknowledges obligations to provide effective protection and enforcement of undisclosed test or other data submitted as a condition of marketing approval, the Phase One Trade Agreement does not contain any specific provisions on data exclusivity.[34]

The National Medical Products Administration of China, however, issued draft guidelines in 2018 on the implementation of drug test data protection.[35] As discussed above, these draft guidelines included data protections for new drugs, new biologics, orphan drugs, drugs with pediatric indications, and generic drugs with successful patent challenges.[36] In view of the draft guidelines, there are promising indications that data exclusivity protection will likely be available in China.

III. Practical Considerations Going Forward

China's ongoing intellectual property and regulatory reforms, along with its commitments under the Phase One Trade Agreement, create new opportunities for drug companies in China. A



"Hatch-Waxman inspired" system in China can offer meaningful protection against at-risk launches of high-value drugs, and potentially avoid the need for protracted litigation over damages due to the marketing and sale of infringing products. In addition, the availability of patent term extensions to compensate for delays in the patent grant and regulatory review periods can incentivize investment in product launches in China. As the Chinese market continues to develop, companies should periodically evaluate their business and legal objectives in China's growing pharmaceutical market and leverage new opportunities to the extent possible. We are already seeing public disclosures of Chinese companies partnering with U.S. and non-U.S. companies with an interest in U.S. drug sales.[37] This trend would be expected to accelerate as China further incentivizes companies to focus on drug innovation in its substantial domestic market.

In addition, companies marketing drug products in the U.S. and China should anticipate and be prepared to litigate parallel patent infringement proceedings in both countries. To prepare for parallel litigations, counsel must have a firm understanding of the nuances of the applicable law in both countries, and should not overlook the considerable differences between the U.S. and Chinese legal systems relevant for patent litigations. For example, in Chinese patent litigations, there is an initial bifurcation of infringement issues to trial courts and validity issues to the patent office.[38] Counsel should also develop coordinated litigation strategies early on, as litigation strategies, inventor statements, and outcomes on infringement and validity disputes in one country may impact the other. Companies should also ensure that litigation positions taken in a non-U.S. forum do not adversely impact U.S. litigation, given the different legal standards. As in the past, collaboration between U.S. and non-U.S. counsel will be important.

As China's intellectual property policy and law continue to evolve, drug companies with business interests in China should closely monitor the relevant developments and the potential impact on their business. Interested companies could also consider submitting comments to various draft laws and regulations released by the Chinese government for public comment, including the proposed implementation measures in accordance with the Phase One Trade Agreement that will be released in the near future.

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[1] 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 Trade Agreement"), at Art. 1.11 (Jan. 15, 2020).

[2] *Id*. at Art. 1.12.

[3] *The Global Use of Medicine in 2019 and Outlook to 2023*, IQVIA Inst. at 12 (2019).

[4] Brian Yang, *10 Commercial Trends to Watch in China in 2020*, Script Informa Pharma Intelligence (Jan. 9, 2020), https://scrip.pharmaintelligence.informa.com/SC141429/10-Commercial-Trends-To-Watch-In-China-in-2020.

[5] *Id*.

[6] The NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, 2018 Annual Drug Review Reports (July 1, 2019).

[7] *Id*.

[8] *E.g.*, THE GENERAL OFFICE OF CHINA'S STATE COUNCIL, Official Opinion on Deepening the Review and Approval Policy Reform and Encouraging Drug and Medical Device Innovations (Aug. 9, 2015); THE STATE FOOD AND DRUG ADMINISTRATION OF CHINA, Policies Regarding the Promotion and Protection of Innovators' Rights in Pharmaceutical Products and Medical Devices (Draft for Public Comment) (May 12, 2017); THE STATE FOOD AND DRUG ADMINISTRATION OF CHINA, Catalogue of Marketed Drugs in China (Sept. 4, 2017); THE GENERAL OFFICE OF CHINESE COMMUNIST PARTY'S CENTRAL COMMITTEE AND THE GENERAL OFFICE OF CHINA'S STATE COUNCIL, Official Opinion on Deepening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (Oct. 8, 2017); The NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, Guidelines on the Implementation of Drug Test Data Protection (Interim) (*Draft Guidelines for Public Comment*) (Apr. 25, 2018); Drug Administration Law of China (Aug. 26, 2019); *The Rewards of Regulatory Change: Launching Innovative Biopharma in China*, Deloitte Insights (2019).

[9] *E.g.*, THE GENERAL OFFICE OF CHINA'S STATE COUNCIL, Official Opinion on Deepening the Review and Approval Policy Reform and Encouraging Drug and Medical Device Innovations (Aug. 9, 2015); THE STATE FOOD AND DRUG ADMINISTRATION OF CHINA, Catalogue of Marketed Drugs in China (Sept. 4, 2017); THE GENERAL OFFICE OF CHINESE COMMUNIST PARTY'S CENTRAL COMMITTEE AND THE GENERAL OFFICE OF CHINA'S STATE COUNCIL, Official Opinion on Deepening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (Oct. 8, 2017); CHINESE NATIONAL MEDICAL PRODUCTS ADMINISTRATION, Database on the Disclosure of Patent Information Related to Drug Registration, http://qy1.sfda.gov.cn/datasearchcnda/face3/base.jsp?tableId=25&tableName=TABLE25&title=%E5%9B%BD%E4%BA%A7%E8%8D%AF%E5%93%81&bcId=152904713761213296322795806604.

[10] THE STATE FOOD AND DRUG ADMINISTRATION OF CHINA, Policies Regarding the Promotion and Protection of Innovators' Rights in Pharmaceutical Products and Medical Devices (Draft for Public Comment) (May 12, 2017).

[11] THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, Guidelines on the Implementation of Drug Test Data Protection (Interim) (*Draft Guidelines for Public Comment*) (Apr. 25, 2018).

[12] Drug Administration Law of China, Chs. 2, 10, 11 (Aug. 26, 2019).

[13] THE SUPREME PEOPLE'S COURT OF CHINA, Guidelines Regarding the Intellectual Property Court of the Supreme People's Court of China (Dec. 27, 2018).

[14] Amended Chinese Patent Law (Draft), Art. 43 (Jan. 4, 2019).

[15] THE GENERAL OFFICE OF THE CPC CENTRAL COMMITTEE OF CHINA AND THE GENERAL OFFICE OF THE STATE COUNCIL OF CHINA, Opinion on Enhancing Intellectual Property Protection (Nov. 24, 2019).

[16] Phase One Trade Agreement, Arts. 1.10–1.12, 1.18, 8.3(1).

[17] *Id*. at Art. 1.35.

[18] *Id*. at Art. 8.5.

[19] *Id*. at Art. 1.11.

[20] *Id*.

[21] *See* 21 U.S.C. § 355.

[22] Phase One Trade Agreement, Art. 1.35.

[23] THE STATE FOOD AND DRUG ADMINISTRATION OF CHINA, Policies Regarding the Promotion and Protection of Innovators' Rights in Pharmaceutical Products and Medical Devices (Draft for Public Comment) (May 12, 2017).

[24] *Id*.

[25] Phase One Trade Agreement, Art. 1.12.

[26] *Id.* at Art. 1.12(2)(a).

[27] Amended Chinese Patent Law (Draft), Art. 42 (Jan. 4, 2019).

[28] Phase One Trade Agreement, Art. 1.10.

[29] THE STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Patent Examination Guidelines (1993, 2001, 2006, 2010).

[30] THE STATE INTELLECTUAL PROPERTY OFFICE OF CHINA, Patent Examination Guidelines, § 2, Ch. 10, Art. 3.5 (2017) ("Examiners shall review experimental data submitted after the application date. The technical effect proven by the supplementary experimental data should be discerned by a person of ordinary skill in the art from the disclosures in the patent application."); THE SUPREME PEOPLE'S COURT OF CHINA, Draft Guidelines on Adjudication Regarding Patentability and Validity, § 13 (2018) ("Courts shall consider experimental data submitted by a patent applicant or patentee for chemical inventions after the application filing date, to further establish that a technical effect described in the specification has been sufficiently disclosed, and such a technical effect can be discerned by a person of ordinary skill in the art in view of the patent specification, patent figures, and common knowledge. Courts shall consider experimental data submitted by a patent applicant or patentee for chemical inventions after the application filing date, to show that the patent application or patent has a different technical effect from the prior art, and such a technical effect can be directly and unambiguously discerned by a person of ordinary skill in the art from the patent document as of the application filing date.").

[31] Phase One Trade Agreement, Art. 1.18(2)(a)–(b).

[32] *Id.* at Art. 1.18(2)(c).

[33] Amended Chinese Drug Administration Law, Chs. 10, 11 (Aug. 26, 2019).

[34] Phase One Trade Agreement, Ch. 1, § C, Preamble.

[35] THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, Guidelines on the Implementation of Drug Test Data Protection (Interim) (*Draft Guidelines for Public Comment*) (Apr. 25, 2018).

[36] *Id*.

[37] Brian Yang, *10 Commercial Trends to Watch in China in 2020*, Script Informa Pharma Intelligence (Jan. 9, 2020), https://scrip.pharmaintelligence.informa.com/SC141429/10-Commercial-Trends-To-Watch-In-China-in-2020.

[38] Renjun Bian, *Patent Litigation in China: Challenging Conventional Wisdom*, 33 Berkeley Tech. L.J. 413, 417 (2018).