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China's Proposals to Provide a Patent Linkage System and Patent Term Extensions – Considerations for Drug Companies

By Melanie R. Rupert, Mi Zhou, Mark Russell Sperling & Jake Silvers

This month, the National People's Congress of the People's Republic of China released the second draft of the amendments to the Chinese patent law ("Second Draft Amendments") for public comment.[1] The Second Draft Amendments include provisions that would provide a "patent linkage" system (drawing from the U.S. Hatch-Waxman Act) for the early resolution of patent infringement disputes before competitor drugs may be launched.[2] The Second Draft Amendments would also provide patent term extensions to compensate for "unreasonable delays" during patent examination and for the time spent during regulatory review.[3] The deadline to submit comments to the Second Draft Amendments is August 16, 2020.[4]

The Second Draft Amendments are among the earliest legislative developments as China begins to implement its commitments to enhance intellectual property protection under the economic and trade agreement between the United States and China ("Phase One Trade Agreement") signed on January 15, 2020. [5] For more information on the pharmaceutical-related intellectual property provisions in the Phase One Trade Agreement, please see our January 23, 2020 article here. This article provides an overview of the pharmaceutical-related provisions in the Second Draft Amendments and potential considerations for drug companies with business interests in China.

I. Efforts to Reform the Chinese Patent Law Before the U.S.-China Phase One Trade Agreement

China is the second largest pharmaceutical market globally.[6] Numerous global drug companies saw accelerated revenue growth in China in 2019.[7] In recent years, China has seen explosive growth in new drug development, ranging from innovative antibodies to new cell therapies.[8] Unsurprisingly, China has witnessed a record increase in the filing and approval of drug applications.[9] In 2018, for example, the Center for Drug Evaluation of the National Medical Products Administration of China completed review of over 9,000 drug applications and received over 7,000 drug applications (including 457 investigational new drug applications, 157 new drug applications, and 123 biologics applications).[10]

Like the U.S. Hatch-Waxman Act, the Chinese patent law provides a safe harbor from a claim of patent infringement if the manufacture, use, or importation of patented drugs or medical devices is made for purposes of providing information needed for regulatory approval in China.[11] Unlike the

Hatch-Waxman Act, however, the Chinese patent law does not provide a mechanism for litigating patent infringement disputes before competitor drugs may be launched.[12] Also in contrast to U.S. law, the Chinese patent law does not compensate for delays in patent grant or for the time spent before the Chinese administrative regulatory authority in obtaining marketing approval of new drugs.[13]

On January 4, 2019, the National People's Congress of China released a draft of amendments to the Chinese patent law ("First Draft Amendments").[14] The First Draft Amendments did propose patent term extensions to compensate for the time spent in obtaining drug marketing approval, but did not provide a mechanism for the early resolution of drug patent infringement disputes or compensate for delays in patent examination.[15] The First Draft Amendments have not passed into law.

II. Pharmaceutical-Related Provisions in the Second Draft Amendments to the Chinese Patent Law

Under the U.S.-China Phase One Trade Agreement signed on January 15, 2020, China committed to enhance intellectual property protection.[16] The Phase One Trade Agreement outlines the general framework of China's commitments but leaves open many details about implementation.[17] At least some details seem to be addressed, however, in the Second Draft Amendments.

Patent Linkage Mechanism for Early Resolution of Drug Patent Disputes

The Second Draft Amendments to the Chinese patent law would revise the First Draft Amendments released in 2019 to provide a patent linkage system for the early resolution of patent infringement disputes before competitor drugs may be launched in China.[18] The proposed patent linkage mechanism is consistent with China's commitments under the Phase One Trade Agreement and draws from the U.S. Hatch-Waxman framework for resolving patent disputes involving small molecule drugs. There are, however, significant differences between the proposed patent linkage mechanism in China and the U.S. Hatch-Waxman system. A comparison of the key differences is in the table below.

Key Provisions	Second Draft Amendments to the Chinese Patent Law[19]	U.S. Hatch-Waxman Act[20]
Notification process	The Chinese drug administration publishes the filing of drug applications	A generic drug company that submits an abbreviated new drug application ("ANDA") that includes a challenge to at least one drug patent listed in the Orange Book must send a notice letter to the holder of a new drug application ("NDA holder") and patent owner
Deadline to commence patent infringement actions	Within 30 days of the publication of the filing of the drug application by the Chinese drug administration	Within 45 days of the receipt of a notice letter from an ANDA filer
Venue for patent infringement actions	People's Court or patent administration	Federal district court

Key Provisions	Second Draft Amendments to the Chinese Patent Law[19]	U.S. Hatch-Waxman Act[20]
Declaratory judgment actions by drug applicants	If the patent owner or interested party does not timely file suit or request an administrative ruling on infringement, the generic drug applicant may file suit or request an administrative ruling on noninfringement	If the patent owner does not timely file a complaint for infringement, the ANDA filer may seek a declaratory judgment of noninfringement
Challenge-based stay of approval of competitor drugs	No express language mandating a stay of approval of competitor drugs In cases where the People's Court or the patent administration issues a decision or administrative ruling within ***nine months*** from the date of acceptance of the request by the patent owner or interested party, the drug administration can determine, in accordance with the decision or administrative ruling, whether or not to grant the marketing approval of a drug application that has received approval under technical review	Generally, up to a ***30-month*** stay from the date of receipt of a notice letter, as long as a patent infringement suit is brought within 45 days
Dissatisfaction with administrative rulings	May file suit in People's Court within 15 days from the administrative ruling	N/A

Under the Second Draft Amendments, the Chinese drug administration and the Chinese patent administration would formulate detailed guidelines on the patent linkage system, subject to approval by the State Council of China.[21]

Patent Term Extension

Under the Second Draft Amendments, the term of a Chinese patent may be adjusted to compensate for "unreasonable delays" that occur during patent examination.[22] To qualify for the adjustment, the patent must be granted more than four years after the Chinese patent application is filed and more than three years after the applicant requests substantive examination in China.[23] Any unreasonable delays caused by patent applicants are excluded from the adjustment. [24] The Second Draft Amendments do not define the term "unreasonable delay."

Like the U.S. patent law, the Second Draft Amendments would provide up to five years of patent term extensions to compensate for the time spent during the regulatory review of a new drug in China, provided that the resulting effective patent term is no more than 14 years from the marketing of the new drug in China.[25]

III. Practical Considerations Going Forward

As China continues to reform its patent law and implement its commitments to enhance intellectual property protection, drug companies with business interests in China should closely monitor relevant developments, adjust their legal strategies accordingly, and evaluate the potential impact on their business. For example, the availability of patent term extensions may provide incentives to invest in product launches in China. The introduction of a patent linkage system may also fundamentally change how drug companies litigate patent disputes, plan product launches, and manage product lifecycles in China. In 2019, there were a number of at-risk launches of high-value drugs in China.[26] For innovative drug companies, a mechanism that provides a meaningful stay of the marketing approval of competitor drugs pending patent litigation in China could be key in minimizing the risk of this scenario. Interested companies should carefully evaluate their business objectives and consider submitting comments to the Second Draft Amendments by August 16, 2020.

In addition to these developments in patent law, interested companies should also closely monitor the ongoing drug regulatory and judicial reforms relevant for patent litigations in China. With respect to drug regulatory reforms, China has been exploring potential non-patent exclusivity protection for drug test data and has previously released draft regulatory guidelines on this topic.[27] Separately, China has been building an online database of approved drugs and drug patents analogous to the U.S. FDA's Orange Book.[28] With respect to judicial reforms, since 2014, a number of specialized intellectual property tribunals at the lower trial court level have been established to adjudicate intellectual property cases throughout China.[29] In addition, 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.[30] Staying current on these developments is key to ensuring the best chances of success.

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, drug companies can look to U.S. Hatch-Waxman cases to help anticipate potential issues that may arise in Chinese litigations. U.S. and Chinese counsel should collaborate early and develop coordinated litigation strategies, as litigation strategies, inventor statements, and outcomes on infringement and validity disputes in one country may impact the other. Counsel should also be mindful of the nuances of the applicable law in both countries, including the considerable differences between the U.S. and Chinese patent law and the legal systems relevant for patent litigations. 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.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

Melanie R. Rupert
1.212.318.6846
melanierupert@paulhastings.com

Mi Zhou
1.212.318.6809
mizhou@paulhastings.com

Mark Russell Sperling
1.212.318.6738
marksperling@paulhastings.com

Jake Silvers
1.212.318.6074
jakesilvers@paulhastings.com

[1] THE NATIONAL PEOPLE'S CONGRESS OF THE PEOPLE'S REPUBLIC OF CHINA, Amendments to the Patent Law of the People's Republic of China (Draft) (Second Deliberation Draft) ("Second Draft Amendments") (July 3, 2020).

[2] *Id*. at ¶ 27 (amendments to revise the current Art. 69 as Art. 75).

[3] *Id*. at ¶ 12 (amendments to Art. 42).

[4] Seeking Comments to Amendments to the Patent Law (Second Deliberation Draft), http://www.npc.gov.cn/flcaw/userIndex.html?lid=ff80808172b5fee8017313b6232c2b55.

[5] *See* 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 Arts. 1.11, 1,12 (Jan. 15, 2020).

[6] *The Global Use of Medicine in 2019 and Outlook to 2023*, IQVIA Inst. at 12 (2019); 2020 China Life Sciences and Healthcare M&A Trends Report, Deloitte (Feb. 2020).

[7] 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.

[8] *E.g.*, *id.*; 2020 China Life Sciences and Healthcare M&A Trends Report, Deloitte (Feb. 2020).

[9] *E.g.*, the NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, 2018 Annual Drug Review Reports (July 1, 2019); Brian Yang, *New China Indications For Merck, Novo, Boehringer Drugs*, Pink Sheet Informa Pharma Intelligence (June 28, 2020), https://pink.pharmaintelligence.informa.com/PS142450/New-China-Indications-For-Merck-Novo-Boehringer-Drugs.

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

[11] The Patent Law of the People's Republic of China, at Art. 69, § 5 (2008).

[12] *Id*.

[13] *Id*.

[14] THE NATIONAL PEOPLE'S CONGRESS OF THE PEOPLE'S REPUBLIC OF CHINA, Amendments to the Patent Law of the People's Republic of China (Draft) (Jan. 4, 2019).

[15] *Id.* at ¶ 7 (amendments to Art. 42).

[16] Phase One Trade Agreement, at Arts. 1.11, 1,12.

[17] *See id*.

[18] Second Draft Amendments, at ¶ 27 (amendments to revise the current Art. 69 as Art. 75).

[19] *Id*.

[20] 21 U.S.C. § 355(j).

[21] Second Draft Amendments, at ¶ 27 (amendments to revise the current Art. 69 as Art. 75).

[22] *Id*. at ¶ 12 (amendments to Art. 42).

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] Zhouhuang Lu, *Dilemma: Is There a Trend for Generic Drugs to Launch At-Risk During the Patent Term?*, China Intellectual Property, Vol. 153, 34-41 (Nov. 2019).

[27] 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).

[28] <http://www.nmpa.gov.cn>.

[29] THE SUPREME PEOPLE'S COURT OF CHINA, I*nterview Series V of the Working Report from the Supreme People's Court* (Mar. 16, 2018), http://www.court.gov.cn/fabu-xiangqing-85572.html.

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