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Takeaways from China's Proposed Regulation to Implement a Drug Patent Linkage System

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In recent years, China has seen explosive growth in new drug development, and a record increase in the filing and approval of drug applications.[1] In 2019, for example, the Center for Drug Evaluation of the National Medical Products Administration of China received and approved over 8,000 drug applications.[2] China is now the second largest pharmaceutical market globally.[3]

To promote innovation and improve patient treatment access, China has been evaluating a patent linkage system since at least 2017.[4] On January 15, 2020, China had agreed to provide a patent linkage system under the economic and trade agreement between the United States and China ("Phase One Trade Agreement").[5] For more information on that previous development, please see our January 23, 2020 article here. On July 3, 2020, China released draft amendments to Chinese patent law, which proposed to provide a patent linkage system and to delegate rule-making authority to the Chinese drug administration and the Chinese patent administration for detailed implementation measures.[6] For more information on that development, please see our July 27, 2020 article here.

Most recently, on September 11, 2020, China's National Medical Products Administration and China's National Intellectual Property Administration jointly released a draft regulation, titled "Measures for the Implementation of a Mechanism for Early Resolution of Drug Patent Disputes (Trial) (Draft for Comments)" ("Draft Regulation").[7] Under the Draft Regulation to implement the patent linkage system, market authorization of competitor drugs in China and the resolution of related patent disputes would be coordinated.[8] Comments are being solicited for the Draft Regulation through October 25, 2020.[9]

The creation of a patent linkage system could reshape drug patent litigation in China. This article reviews the key features of the Draft Regulation and provides takeaways for drug companies.

I. Draft Regulation on the Implementation of the Patent Linkage System

The Draft Regulation follows China's agreement under the Phase One Trade Agreement, as well as the general framework set forth in the draft amendments to the Chinese patent law. The proposal for the patent linkage system draws on the resolution of patent disputes under the Hatch-Waxman Act in the United States.

There are, however, significant differences between the proposed patent linkage system in China and the Hatch-Waxman system, which we set forth in the table below. For example, in the United States, the Hatch-Waxman system only concerns small molecule drugs, and the resolution of drug patent

disputes before the launch of biologic drugs is governed by the Biologics Price Competition and Innovation Act. In contrast, the proposed Chinese system concerns both small molecule and biologic drugs. China's proposed patent linkage system can also be more favorable to generic drug companies than the U.S. system.

Key Provisions	China's Proposed Patent Linkage System	U.S. Patent Linkage System Under Hatch-Waxman Act
Submission of drug patent information	For small molecule drugs, the holder of a drug application may submit patents covering (1) the active ingredient; (2) pharmaceutical composition comprising the active ingredient; and (3) medical use[10] For biologic drugs, the holder of a drug application may submit patents covering biological sequences[11]	A drug company that submits a new drug application ("NDA") must inform the FDA patents covering (1) the active ingredient; (2) the drug product (formulation and composition); and (3) method of treatment for which approval is sought or has been granted[12]
Drug patent database	For small molecule and biologic drugs, drug patent information is published on China's marketed drug patent information registration platform[13]	Drug patent information is published on an FDA website commonly known as the "Electronic Orange Book"[14]
Patent certifications to administrative agency	For small molecule and biologic drugs, a competitor drug applicant must make one of the following patent certifications, as applicable and with regard to each listed patent: (I) no patent information on the innovator drug is listed on China's marketed drug patent information registration platform; (II) the patent has expired or been declared invalid; (III) competitor drug will not be launched before expiration of the patent; or (IV) the patent should be declared invalid or is not infringed[15]	A generic drug company that submits an abbreviated new drug application ("ANDA") shall make one of the following patent certifications, as applicable and with regard to each listed patent: (I) patent information on the innovator drug has not been filed; (II) the patent has expired; (III) the date on which the patent will expire; or (IV) the patent is invalid, unenforceable or not infringed[16]

Key Provisions	China's Proposed Patent Linkage System	U.S. Patent Linkage System Under Hatch-Waxman Act
Notification process	For small molecule and biologic drugs, the Chinese drug administration publishes the filing of competitor drug applications and patent certifications[17]	An ANDA filer that makes a Paragraph IV certification shall send a notice letter to the NDA holder and patent owner[18]
Confidential access to competitor drug applications	No requirement to provide confidential access to the competitor drug application	An ANDA filer that makes a Paragraph IV certification shall provide confidential access of its ANDA to the NDA holder and patent owner for the sole and limited purpose of evaluating possible patent infringement suit[19]
Deadline to commence patent infringement proceedings	For small molecule and biologic drugs, within 45 days of the publication of the filing of the competitor drug application by the Chinese drug administration[20]	Within 45 days of the receipt of a notice letter from an ANDA filer[21]
Venue for patent infringement proceedings	People's Court or patent administration[22]	Federal district court[23]
Civil action by competitor drug applicants to obtain certainty	No express language in the Draft Regulation Under the draft amendments to the Chinese patent law, if the patent owner or interested party does not timely file suit or request an administrative ruling on infringement, the competitor drug applicant may file suit or request an administrative ruling on noninfringement[24]	If the patent owner does not timely file infringement suit, the ANDA filer may seek a declaratory judgment of noninfringement[25]
Stay of marketing approval of generic drug applications pending litigation	For small molecule drugs, up to a 9-month stay from the date the complaint is accepted by People's Court or patent administration, if a patent infringement suit or administrative proceeding is timely brought[26]	Generally, up to a 30-month automatic stay from the date of receipt of a Paragraph IV notice letter, if a patent infringement suit is timely brought[28]

Key Provisions	China's Proposed Patent Linkage System	U.S. Patent Linkage System Under Hatch-Waxman Act
	For biologic drugs, there is no automatic litigation stay unless the biosimilar drug is found infringed before it receives marketing approval[27]	
Exclusivity for generic drugs	For small molecule drugs, a generic drug applicant that is the first to (1) succeed in the patent challenge, (2) obtain approval and market the drug will be eligible for a one-year exclusivity, provided that the exclusivity does not exceed the term(s) of the patent(s) challenged[29]	Eligibility for 180-day exclusivity for each ANDA filer that is the first-to-file a Paragraph IV certification with respect to any listed patent[30]
Liability for submitting improper patent information or bad faith patent certification	Drug companies and their agents that willfully submit improper patent information for listing or any false patent certification will be legally liable and may be barred for a year from registering the same drug[31]	Drug companies and their agents that submit improper patent information for listing or any bad faith patent certification may face civil and criminal liability[32]

II. Practical Considerations Going Forward

The creation of a patent linkage system could reshape drug patent litigation in China. An automatic stay of marketing approval of generic drugs pending patent litigation could help innovator drug companies to address the current practice of at-risk launches in China. Innovator drug companies, however, should also note the potential challenges to litigating under the proposed Chinese patent linkage system in China. For example, under the Draft Regulation, competitor drug applicants are not required to provide their drug applications during the pre-litigation period. Also, to avoid at-risk launches, infringement rulings need to be obtained within the 9-month stay period. Additionally, in view of the potential for one-year market exclusivity, generic drug companies would have significant incentives to challenge patents that block generic entry. Interested companies should carefully evaluate the Draft Regulation and consider submitting comments by October 25, 2020.

Innovator drug companies with business interests in China should also consider adjusting their legal strategies and practices applicable there in accordance with the proposed patent linkage system. For example, during patent prosecution in China, it would be important to pursue claims that meet the requirements for drug patent listing. It would also be critical to create a reliable system that monitors, preferably on a daily basis, the official publication of competitor drug application filings and patent challenges. Unlike in the United States, where generic drug applicants must notify the patent owner of their patent challenges, in China, the official publication of competitor drug application filings and patent certifications constitutes "notice" on the patent owner. It also triggers the 45-day deadline for

the patent owner to commence an infringement proceeding, which is required for obtaining a litigation stay.

Drug companies marketing products internationally should also prepare for parallel patent challenges across multiple jurisdictions, including China. The availability of a one-year market exclusivity may make this a more common practice. Also, the Chinese infringement proceedings can progress extremely fast, potentially within nine months from filing to decision. Thus, drug companies should consider preemptively engaging in pre-suit analyses of key patents and be ready for challenges. As is often the case now with respect to European and Canadian life sciences patent challenges, it may become more important to have coordination with Chinese patent litigation as well.

As China continues to develop its drug patent law, those with business interests in China should closely monitor relevant developments and quickly adjust their legal and business strategies. Staying current on these developments is critical for legal and business success.

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1 *E.g.*, 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; 2020 China Life Sciences and Healthcare M&A Trends Report, Deloitte (Feb. 2020); THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, 2019 Annual Drug Review Reports (July 30, 2020).

2 *Id*.

3 *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).

4 *See*, *e.g.*, CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION AND CHINA'S NATIONAL INTELLECTUAL PROPERTY ADMINISTRATION, Drafting Commentaries With Regard to "Measures for the Implementation of a Mechanism for Early Resolution of Drug Patent Disputes (Trial) (Draft for Comments)" (Sept. 11, 2020).

5 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).

6 Draft amendments to the Chinese patent law, at ¶ 27 (amendments to revise the current Art. 69 as Art. 75) (July 3, 2020).

[7] China's National Medical Products Administration and China's National Intellectual Property Administration, Measures for the Implementation of a Mechanism for Early Resolution of Drug Patent Disputes (Trial) (Draft for Comments) ("Draft Regulation") (Sept. 11, 2020).
[8] *Id*.
[9] The General Affairs Department of the National Medical Products Administration and the National Intellectual Property Administration jointly seek public comments to "Measures for the Implementation of a Mechanism for Early Resolution of Drug Patent Disputes (Trial) (Draft for Comments)" (Sept. 11, 2020), https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200911175627186.html.
[10] Draft Regulation, at Art. 5.
[11] *Id*. at Art. 12.
[12] 21 C.F.R. § 314.53.
[13] Draft Regulation, at Arts. 3, 12.
[14] U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
[15] Draft Regulation, at Arts. 6, 12.
[16] 21 U.S.C. § 355(j)(2)(A)(vii).
[17] Draft Regulation, at Arts. 6, 12.
[18] 21 U.S.C. § 355(j)(2)(B)(iv)(II).
[19] 21 U.S.C. § 355(j)(5)(C)(i)(III).
[20] Draft Regulation, at Arts. 7, 12.
[21] 21 U.S.C.§ 355(j)(5)(B)(iii).
[22] Draft Regulation, at Arts. 7, 8, 10, 12.
[23] 28 U.S.C. §§ 1331, 1338(a), 2201, 2202; 35 U.S.C. § 271.
[24] Draft amendments to the Chinese patent law, at ¶ 27 (amendments to revise the current Art. 69 as Art. 75).
[25] 21 U.S.C. § 355(j)(5)(C)(i)(I).
[26] Draft Regulation, at Art. 8.
[27] *Id*. at Art. 13.
[28] 21 U.S.C. § 355(j)(5)(B)(iii).
[29] Draft Regulation, at Art. 11.
[30] 21 U.S.C. § 355(j)(5)(B)(iv), (j)(5)(D)(i).
[31] Draft Regulation, at Art. 15.
[32] *E.g.*, *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1 (1st Cir. Feb. 13, 2020) (potential antitrust liability for improper Orange Book listing); 21 C.F.R. § 314.53(c)(2)(i)(Q) (requiring NDA holder to verify "under penalty of perjury" that its submission of Orange Book patent information is true and correct); *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347-48 (Fed. Cir. 2000) (ANDA filer making a baseless patent certification can be liable for attorney fees).