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What to Watch in 2021: Big Changes for Drug Companies in China

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For several years, China has been evaluating changes to its drug approval system to promote drug innovation and patient access to medicines. The year 2020 saw China begin taking steps towards adopting some of those changes. U.S. biopharma companies doing business in China, and those looking to do business in China, should start preparing now for the changes coming in 2021.

> I. Economic and Trade Agreement Between the United States of America and the People's Republic of China (Phase One) signed January 15, 2020 (the "Phase One Trade Agreement")

The year 2020 began with China formally committing, in the Phase One Trade Agreement signed with the United States on January 15th, to establishing a patent linkage system as part of a system for approving generic drug products.[1] The Phase One Trade Agreement obligates China to establish processes to resolve patent disputes before generic market approval (Article 1.11)[2] as well as to provide patent term adjustments and extensions to compensate for unreasonable delays in granting patents and unreasonable curtailment of patent term due to the marketing approval process for a new drug product (Article 1.12). These Hatch-Waxman-type incentives will reshape drug product approval and ensuing patent dispute resolution in China by providing incentives to innovator companies and encouraging generic companies to challenge patents covering innovator drug products.

> II. Draft Measures for Implementation of Early Resolution Mechanisms on Drug Patent Disputes from China's National Medical Products Administration ("NMPA") and China National Intellectual Property Administration ("CNIPA") published September 11, 2020 (the "Draft Administrative Measures")

Prior to formal adoption of amendments to enact China's obligations under the Phase One Trade Agreement into law, China's NMPA and CNIPA jointly issued Draft Administrative Measures for implementing a patent linkage system by which a generic drug product's marketing approval is linked to patents covering the innovator drug product.

Under the Draft Administrative Measures, the NMPA will establish and maintain a drug patent information registration platform (the "Patent Information Registration Platform") similar to the U.S. FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for patentees and innovator drug manufacturers to register drug-related patent information (Article 2). Patents that can be listed in the Patent Information Registration Platform include those for active pharmaceutical ingredients (APIs), compositions

containing APIs, and pharmaceutical uses (Article 5); biologic sequence structures (Article 12);[3] and TCM compositions, extracts and pharmaceutical uses (Article 12).

Similar to the Hatch-Waxman Act, the Draft Administrative Measures would require the generic applicant to submit one of four certifications against each listed patent when seeking marketing authorization.[4] Unlike in the Hatch-Waxman Act, however, there is no requirement under the Draft Administrative Measures for a generic applicant to notify the patent owner or reference innovator drug applicant of a challenge to the validity or scope of a listed patent, or to provide any statement as to the legal and factual basis thereof, or to make an offer of confidential access to the generic application. Rather, the burden is placed on the patentee and innovator to monitor the generic applications and patent certifications published by China's Center for Drug Evaluation ("CDE"), and to file a patent infringement proceeding in court or in the CNIPA against the generic applicant within 45 days from such a publication (Article 7).[5] Within 10 days of the patent proceeding being instituted or accepted, the patentee or innovator must notify the CDE.

Where the generic application is for a pharmaceutical drug product, the NMPA will issue a 9-month stay on approving the application from the date the patent proceeding is filed or accepted by the court or CNIPA (Article 8). The first generic pharmaceutical applicant to succeed in its patent challenge and obtain market approval will receive 12-months marketing exclusivity (not to exceed the patent term) (Article 11). The Draft Administrative Measures do not provide this 9-month stay of approval or 12-months marketing exclusivity for generic biologic or generic TCM applications (Articles 12 & 13).[6]

III. Fourth Amendments to China's Patent Laws, adopted by the National People's Congress ("NPC") on October 17, 2020 (the "Fourth Amendments")

On October 17th, the NPC formally adopted the Fourth Amendments, which implement several of the changes China had pledged to make under the Phase One Trade Agreement. Of particular relevance to the biopharma industry are amended Article 42 and new Article 76 of China's Patent Laws. The Fourth Amendments will take effect on June 1, 2021.

Amended Article 42 now allows for patent term adjustments (due to unreasonable delay during patent prosecution) and patent term extensions (to compensate for marketing review and approval of new drugs). Patent term extensions may extend the term of drug patents for up to five years, provided the term does not to extend marketing of the drug product beyond 14 years.

New Article 76 formally establishes a patent linkage system to allow resolution of patent disputes prior to market approval of generic drug products. Article 76 allows any of the generic applicant, the concerned patentee or any interested party to institute a legal proceeding in the people's court and/or request the CNIPA to adjudicate a patent dispute arising during drug marketing authorization. With regard to CNIPA adjudication of such pre-market approval patent disputes, Article 76 delegates authority to formulate such implementation measures jointly to the

NMPA and CNIPA, which measures shall be implemented upon approval of the State Council.[7]

> IV. Draft Provisions of the Supreme People's Court ("SPC") Concerning Application of Law to the Trial of Patent Civil Cases Involving the Review and Approval of Drug Marketing, published October 29, 2020 ("Draft Judicial Provisions")

China's SPC released the Draft Judicial Provisions on October 29 th, providing its draft provisions for implementing the patent linkage system of new Article 76 of the China Patent Laws.

The Draft Judicial Provisions grant sole jurisdiction for patent civil cases arising under Article 76 of the Patent Laws to the Beijing Intellectual Property Court ("BJIPC") (Draft Judicial Provisions, Article 1) and specifically limit such cases to patents listed in the Patent Information Registration Platform (Articles 2 & 4). Prior to marketing approval, cases involving the same patent and same drug product may be combined before the BJIPC (Articles 5 & 14). The court shall not stay or suspend the civil action in view of any parallel administrative action before the CNIPA (Article 6) but, if the CNIPA declares the patent invalid, the court may dismiss the civil action or adjudge the patent not infringed (Article 8). A patentee or interested party may apply for a preliminary injunction against acts of infringement (making, using, selling, offering for sale, or importing the generic drug product) with provision of a guarantee (bond) but the court will not enjoin the NMPA from acting on a generic drug marketing application or approval (Article 10). The Draft Judicial Provisions also allow a generic applicant to sue for damages and expenses when a patentee or interested party abuses its patent rights (Article 17).

One thing that the Draft Judicial Provisions does not provide is a time frame for the BJIPC to issue its decision. This raises the possibility that the NMPA may grant generic marketing approval before the civil litigation concludes. Once approved, the NMPA generally will not revoke a generic drug product's approval, [8] leaving the patentee or interested party to seek remedies in a separate patent infringement action (Article 15).

With such monumental changes to the biopharma patent and regulatory landscape in China on the horizon for 2021, U.S. innovator drug companies doing business in China should monitor closely for publication of final rules by the NMPA/CNIPA and SPC, review their China patent portfolios and consider adjusting their global legal strategies in anticipation of the Fourth Amendments to China's Patent Laws taking effect on June 1, 2021. Once China's patent linkage system is implemented, it will be imperative for innovator drug companies to provide relevant patent information to the Patent Information Registration Platform and to monitor the CDE's publication of generic applications and patent certifications on a regular basis.

It is even more important now to work with counsel to coordinate regulatory, patent portfolio development and litigation strategies globally. Please contact the authors with any questions and stay tuned for updates to this important amendment to China's Patent Law.

Footnotes

[1] A generic drug product here includes a pharmaceutical, biologic or Traditional Chinese Medicine (TCM) product that relies on safety and efficacy evidence or information for a drug product that was previously approved in China.

[2] Currently, before these proposed changes to China's Patent Laws are fully implemented, a patent owner can only sue a generic drug manufacturer for patent infringement after the generic drug product has hit the market.

[3] The Draft Administrative Measures only provide for patent listing of sequence structures for biologics, not for listing of patents claiming biologic compositions or biologic medical uses.

[4] The four categories of patent certifications under the Draft Administrative Measures are similar to the patent certification categories under the Hatch-Waxman Act, namely:
Category I: No relevant patent is listed on the platform;
Category II: The relevant listed patent has expired or was invalidated;
Category III: The generic drug product will not enter the market before the expiration of the relevant listed patent; and
Category IV: The generic applicant believes the relevant listed patent to be invalid or not infringed.

[5] While patent infringement claims may be brought before the courts or before the local offices of the CNIPA, only the CNIPA may resolve challenges to patent validity.

[6] Rather, the Draft Administrative Measures provide that the NMPA will proceed with technical review of generic biologic and TCM drug applications regardless of any patent challenge filed within the 45 day period after publication by CDE (Articles 12 & 13); if, before NMPA concludes its examination and approval process, a court or CNIPA determines the generic drug product infringes a listed patent, then NMPA will approve the application with a note that marketing and sales are only allowed after the patent expires (Article 13).

[7] As discussed previously, the NMPA and CNIPA jointly published the Draft Administrative Measures on September 11, 2020.

[8] The Draft Administrative Measures clearly articulate that, after a generic drug is approved, the NMPA's decision on marketing approval shall not be revoked and its effectiveness shall not be affected by the outcome of any patent challenge (Article 14).