Updates
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Three Changes to Pharmaceutical Patents in the PRC

This update addresses three important changes to pharmaceutical patents in the People's Republic of China (PRC) in view of the newly amended PRC Patent Law (the Law), which will take effect on June 1, 2021, and the recent amendments to the Patent Examination Guidelines (the 2021 Guidelines) that took effect on January 15, 2021. These changes involve (1) patent term compensation due to delay in patent prosecution and/or marketing approval; (2) patent linkage system for pharmaceutical patents; and (3) relaxed criteria for consideration of post-filing data in patent prosecution. These changes aim to improve patent protection and enhance patent value for inventions in the PRC; they are also consistent with matters addressed in the *Economic And Trade Agreement Between the Government of the United States of America And the Government of the People's Republic of China* (the Agreement) issued January 15, 2020.

Patent Term Compensation

The Law provides potential patent term compensation not only to pharmaceutical patents but also to all invention patents that are granted at least four years from the filing date and more than three years after the request of substantive examination.[1] A compensation for "unreasonable delays" caused by the intellectual property (IP) administration during prosecution may be requested by patentee.[2] Furthermore, invention patents "related to new drugs that receive marketing approval in China" may also receive patent term compensation for the delay during marketing approval.[3] However, the maximum patent term compensation for marketing approval is five years, and the maximum effective patent term after the drug is approved is 14 years.[4]

Patent Linkage System: "Artificial" Act of Infringement

The Law also provides mechanisms for early resolution of pharmaceutical patent disputes *during*, rather than after, marketing approval of a generic drug.[5] Patentees and interested parties may adjudicate a patent dispute before a court or state patent administration authority before generic drugs are approved. The state drug administration authority may stay the approval process based on the decision in the dispute. Both the National Medical Products Administration (NMPA) and the China National Intellectual Property Administration (CNIPA) issued drafts of measures for public comments. The Supreme People's Court also issued a draft judicial interpretation on the same for public comments. The Draft Implementing Measures provide more guidance on (1) setting up a platform for patent information of approved drugs in the PRC;[6] (2) four types of patent declarations made by generic applicants;[7] (3) different approval processes for generic applicants making different types of patent declarations, especially for generic applicants who make a type 4 patent declaration;[8] (4) a stay of nine months for approval of the generic application if a patent dispute is initiated;[9] and (5) marketing exclusivity of up to 12 months for the first generic drug approved.[10]

Post-Filing Data

Examples are provided to clarify when Examiners should accept post-filing data in the 2021 Guidelines that took effect on January 15, 2021. The 2021 Guidelines require Examiners to accept post-filing data that prove

"technical effects that one person of ordinary skill in the art can derive from the original disclosure."[11] In prior practice, Examiners often reject post-filing data for technical effects that are merely stated in the disclosure without experimental data. However, according to the first example provided in the 2021 Guidelines, Examiners should accept post-filing data for a technical effect if the original disclosure discloses the technical effect and a method for measuring the technical effect, even if the original disclosure does not disclose experimental data for the technical effect.

Endnotes

[1] The Law, Article 42(2).

[2] This is similar to the patent term adjustment for U.S. patents due to delays caused by the USPTO ("PTA"); see also the Draft Implementing Regulations of the Patent Law issued November 27, 2020 for public comments, Articles 85 and 100(1), downfile.jsp (cnipa.gov.cn).

[3] The Law, Article 42(3); similar to the patent term extension (PTE) provided for U.S. patents to compensate for marketing approval.

[4] Id.

[5] The Law, Article 76; similar to the "artificial" act of infringement practice in the U.S.

[6] The Draft Implementing Measures, Articles 2-5; similar to the orange book in the U.S.

[7] The Draft Implementing Measures, Article 6; similar to paragraphs I-IV certifications to FDA in the U.S.

[8] The Draft Implementing Measures, Article 10; similar to paragraph IV challenge in the U.S.

[9] The Draft Implementing Measures, Article 8.

[10] The Draft Implementing Measures, Article 11.

[11] The 2021 Guidelines, Pt. 2, Ch. 10, § 3.5.1.

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