Updates
June 04, 2021
Updates on the Implementation of the Newly Amended PRC Patent Law

The China National Intellectual Property Administration (CNIPA) and the National Medical Products Administration (NMPA) in the People's Republic of China (PRC) issued measures to facilitate the implementation of the newly amended PRC Patent Law (the Law), which took effect on June 1, 2021. The measures involve (1) the interim measures for the implementation of the Law and (2) the patent linkage registration platform for drugs approved in the PRC.

Interim Measures for the Implementation of the Law

The CNIPA issued the interim measures for processing of related examination businesses regarding the implementation of the Law (the Measures). The Measures took effect on June 1, 2021.

The Measures allow applicants to submit applications or petitions for the following, which will be examined after the implementing regulations of the Law take effect:

- Design patent applications filed on or after June 1, 2021: design patent protection for partial design (the Law, Art. 2(4), the Measures, Art. 1); domestic priority claim (the Law, Art. 29(2), the Measures, Art. 3).
- Grace period for disclosure of patent applications filed on or after June 1, 2021: first disclosure for public interests during a national emergency (the Law, Art. 24(1), the Measures, Art. 1).
- Patent term compensation for invention patents issued on or after June 1, 2021, due to unreasonable delays caused by the CNIPA during prosecution can be requested by the patentee within three months from the issuance of the patent (the Law, Art. 42(2), the Measures, Art. 5).

- Patent term compensation for invention patents "related to new drugs that receive marketing approval in China" for marketing approval can be requested by the patentee within three months from the approval on or after June 1, 2021 (the Law, Art. 42(3), the Measures, Art. 6).

Patent Linkage Registration Platform Launched in the PRC for Public Testing

The Center for Drug Evaluation (CDE) of NMPA launched for public testing a patent information registration platform of drugs approved in the PRC.[1] The CDE further specified (1) which patents are eligible for registration; (2) the deadline for generic applicants to submit a patent declaration; and (3) the four types of patent declarations.

The platform allows registration of patents related to small molecules, biologics, and traditional Chinese medicine. Compound patents, composition patents, and use patents of a drug marketed in the PRC are eligible for platform registration. However, patents claiming intermediates, metabolites, crystalline forms, preparation methods, or detection methods are not eligible for platform registration.[2]

A generic applicant will have 10 days from the medical products administration's receipt of its marketing approval application to provide a notice of patent declaration to the marketing approval holder of the relevant innovative drug.[3]

The four types of patent declarations specified by the CDE are similar to the corresponding paragraph I-IV certifications by the U.S. Food and Drug Administration (FDA), as summarized below.

Type	CDE Patent Declaration[4]	FDA Patent Certification[5]
1	That the relevant patent information has not been registered.	That the patent information has not been submitted to the FDA.
2	That the relevant patent has expired or been invalidated, or the generic applicant has a license for the relevant patent.	That the patent has expired.
3	That the relevant patent information has been registered, but the generic applicant promises that the generic drug will not be marketed before the expiration date of the relevant patent.	The date on which the patent will expire.
4	Type 4.1: That the relevant patent should be invalidated. Type 4.2: That the relevant patent will not be infringed by the generic drug.	That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated new drug application (ANDA) is submitted.

Endnotes

[1] The CDE of the NMPA issued the notice on the public testing of the platform for registration of patent information related to the mechanisms for early resolution of drug patent disputes and other related matters (the Notice) on May 18, 2021. The Notice includes (1) an instruction for the form of registration of patent information of approved drugs in the PRC (the Instruction); (2) a patent information registration template; and (3) a patent declaration template, http://www.cde.org.cn/news.do?method=largeInfo&id=464a59511b09ddfc. *See* https://zldj.cde.org.cn/home for the platform's official website.
[2] The Instruction, § 8.
[3] The patent declaration template.
[4] *Id.*
[5] 21 C.F.R. 314.94.

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