Beijing Intellectual Property Court
Reference for Case Filing in Civil Cases involving Patent Disputes Related to Drugs of Which Applications for Registration are Filed
(Trial Implementation)

This *Reference* is hereby developed, in accordance with the *Patent Law of the People's Republic of China*, *Civil Procedure Law of the People's Republic of China*, and *Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases involving Patent Disputes Related to Drugs of Which Applications for Registration are Filed* etc., to facilitate the parties in cases involving patent disputes related to drugs of which applications for registration are filed to understand relevant requirements of case filing.

Article Ⅰ The Cause of Action

The cause of action for civil cases involving patent disputes related to drugs of which applications for registration are filed is a *dispute over the confirmation of whether the subject matter falls within the scope of patent protection.*

Article Ⅱ Subject Qualification Materials to Be Provided Where the Patentee or Interested Party Files a Lawsuit

The patentee shall provide the duplicate of the patent register, the change records of the bibliographic data on the patent right, the receipt for the patent annual fee, etc., to prove its identity and that the patent involved is valid.

The patent licensee shall further provide, in addition to the above materials, the patent licensing contract, the filing record of the patent licensing contract, or other materials that enable to prove the patent license relationship. The licensee of the exclusive licensing contract may file a lawsuit independently. Where the licensee of the sole licensing contract files a lawsuit independently, in addition to the materials listed above, the said party shall further provide the materials that prove the patentee does not file a lawsuit. Where the licensee of the general licensing contract files a lawsuit independently, in addition to the materials listed above, the said party shall further provide the authorization by the patentee to file a lawsuit in its own name.

The holder of the permit for the marketing of a drug shall provide the drug registration certificate and other approval documents.

Article Ⅲ Subject Qualification Materials to Be Provided

Where the Applicant for the Marketing of a Drug Files a Lawsuit

Where the applicant for the marketing of a drug files a lawsuit as the plaintiff, he or she shall provide the application form for the drug marketing authorization and notification of acceptance of the drug registration application issued by the medical products administration of the State Council.

Article Ⅳ The Definite Defendant

Where the patentee or interested party files a lawsuit as the plaintiff, the applicant for the marketing of a drug shall be listed as the defendant.

Where the applicant for the marketing of a drug files a lawsuit as the plaintiff, the right holder of the patent shall be listed as the defendant.

Article Ⅴ The Specific Claims, Facts and Grounds

Where the patentee or interested party files a lawsuit, the said party shall provide the following materials to prove his claims, facts, and grounds:

1. Relevant patent information disclosed in the *Patent Information Registration Platform For Drug Marketed in China* (hereinafter the

Platform), including the name and number of the patent, and relevant claims, among others;

2. Relevant information of the drug of which an application for registration is filed disclosed in the *Platform*, including the name, type and registration category of the drug, and correlation between the drug of which an application for registration is filed and the involved drug on the market, among others; and

3. Four types of declarations made by the applicant for the marketing of a drug in accordance with *the Implementation Measures for the Mechanism For Early Settlement of Drug Patent Disputes (Trial Implementation)* and the basis for making such declarations.

Where the applicant for the marketing of a drug files a lawsuit, the said party may refer to the above paragraph and provide evidence to prove his or her specific claims, facts, and grounds.

Article Ⅵ The Limitation of Action

Where the patentee or interested party fails to file a lawsuit within 45 days from the date when the national drug evaluation institution discloses the application for drug marketing authorization, the applicant for the marketing of a drug may file a lawsuit. In the said circumstance, the applicant for the marketing of a drug shall provide evidence that

demonstrates the patentee or interested party has not filed a lawsuit within 45 days. The said applicant who is unable to provide the said evidence may provide an relevant explanation.

Article Ⅶ Notarization and Authentication Documents

Where the plaintiff is a foreigner, foreign enterprise or organization, the said party shall provide lawfully notarized and authenticated subject qualification materials when filing a lawsuit. If the plaintiff is a resident, enterprise or organization of *Hong Kong Special Administrative Region* or *Macao Special Administrative Region*, who does not have domicile in Mainland China, the said party shall provide the notarized and transmitted subject qualification materials when filing a lawsuit. Where the plaintiff is a Taiwan resident, enterprise, or organization, who does not have domicile in the Mainland, the said party shall provide subject qualification materials that have been lawfully notarized and have been certificated by *China Notary Association* or *Beijing Notary Association* when filing a lawsuit.

Article Ⅷ Miscellaneous

Other requirements of case filing shall be implemented in

accordance with relevant laws, regulations, and provisions.

Beijing Intellectual Property Court

The Interpretation of

the Reference for Case Filing in Civil Cases involving Patent Disputes Related to Drugs of Which Applications for Registration are Filed

(Trial Implementation)

To better understand the *Reference*, the relevant provisions of the *Reference* are hereby interpreted as follows:

1. On the subject qualification materials to be provided by the Patent Licensee

Article 2 of the *Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in cases involving the Review of act Preservation in Intellectual Property Disputes* stipulates that *where the licensee under an intellectual property licensing contract applies for the issuance of an order to stop the infringement of intellectual property before litigation, the licensee under an exclusive licensing contract may separately file an application with the people's court; the licensee under a sole licensing contract may separately file an application if the rights holder does not file any application; the licensee under a general licensing contract may separately file an application in his or her own name upon specific authorization by the right holder.*

With reference to the above provisions, in the civil cases involving patent disputes related to drugs of which applications for registration are filed where the patent licensee files a lawsuit, the said party shall provide the subject qualification materials in accordance with the above provisions.

2. On the defendant

Considering the common characteristics between the civil cases involving patent disputes related to drugs of which applications for registration are filed and the case concerning confirmation of non-infringement of intellectual property rights, and under the principle established in the judicial precedents, the patentee shall be listed as the defendant where the applicant for the marketing of a drug files a lawsuit as the plaintiff, in the civil cases involving patent disputes related to drugs of which applications for registration are filed.

3. On the notarization and authentication documents of subject qualification involving entity of a foreign state or the *Hong Kong and Macao Special Administrative Region*, or the Taiwan region.

In accordance with the *Answers to the Questions on the Application of Law in Administrative Trials (III)* issued by the Beijing High People's Court, where law firms or relevant agencies represent foreign natural or legal persons in administrative litigations, if the said agent may, within the limitation of action, provide the court with an indictment and fax or e-mail of the power of attorney signed by the client, and provide notarized and authenticated power of attorney to the court within three months

after the litigation, the limitation of action may not be deemed as exceeded. Considering the case involving patent disputes related to drugs of which applications for registration are filed belongs to a civil case, the above provisions are not applicable. Thus, where the plaintiff is an entity of a foreign state or the Hong Kong and Macao Special Administrative Region, or the Taiwan region, it shall provide the required notarization and authentication documents in their entirety upon filing a lawsuit.