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北京知识产权法院关于申请注册的药品相关的专利权纠纷民事案件立案指引（试行）

北京知识产权法院关于申请注册的药品相关的专利权纠纷民事案件立案指引（试行）

引 言

第四次修正的《中华人民共和国专利法》已于2021年6月1日起施行，其中规定了“药品上市审评审批过程中，药品上市许可申请人与有关专利权人或者利害关系人，因申请注册的药品相关的专利权产生纠纷的，相关当事人可以向人民法院起诉，请求就申请注册的药品相关技术方案是否落入他人药品专利权保护范围作出判决。”根据《最高人民法院关于审理申请注册的药品相关的专利权纠纷民事案件适用法律若干问题的规定》，该类纠纷第一审案件，由北京知识产权法院管辖。

为医药行业的自主创新和高质量发展提供有力司法保障，保护药物的可及性和广大人民群众的生命健康，北京知识产权法院根据《中华人民共和国民事诉讼法》以及相关司法解释的规定，制定、发布了《北京知识产权法院关于申请注册的药品相关的专利权纠纷民事案件立案指引（试行）》，以便于申请注册的药品相关的专利权纠纷民事案件当事人明确立案审查阶段的相关事项，希望通过司法实践积累经验，同时听取社会各界的意见建议，加以完善。

北京知识产权法院关于申请注册的药品相关的专利权纠纷民事案件立案指引（试行）

为便于申请注册的药品相关的专利权纠纷民事案件当事人明确立案审查阶段的相关事项，根据《中华人民共和国专利法》《中华人民共和国民事诉讼法》《最高人民法院关于审理申请注册的药品相关的专利权纠纷民事案件适用法律若干问题的规定》等有关规定，制定本指引。

第一条【案由】

申请注册的药品相关的专利权纠纷民事案件案由为“确认是否落入专利权保护范围纠纷”。

第二条【专利权人或者利害关系人提起诉讼时应提交的主体资格材料】

专利权人应提交专利登记簿副本、专利权著录事项变更记录、交纳专利年费的收据等材料证明其专利权人身份及涉案专利处于有效状态。

专利被许可人除需提交前述材料外，还应提交专利许可合同、专利许可备案信息或其他能证明专利许可关系的材料。独占许可合同的被许可人可单独提起诉讼；排他许可合同的被许可人单独提起诉讼的，除应提供前述列举的材料外，还应提供专利权人不提起诉讼的材料。普通许可合同的被许可人单独提起诉讼的，除应提供前述列举的材料外，还应提供专利权人明确授权被许可人以自己的名义提起诉讼的材料。

药品上市许可持有人应提交药品注册证书等批准证明文件。

第三条【药品上市许可申请人提起诉讼时应提交的主体资格材料】

药品上市许可申请人作为原告提起诉讼的，应提交药品上市许可申请表及国务院药品监督管理部门作出的药品注册申请受理通知书。

第四条【明确的被告】

专利权人或者利害关系人作为原告提起诉讼的，应以药品上市许可申请人为被告。

药品上市许可申请人作为原告提起诉讼的，应以专利权人为被告。

第五条【具体的诉讼请求和事实理由】

专利权人或者利害关系人提起诉讼时应提交下列材料证明其诉讼请求及事实理由：（一）中国上市药品专利

信息登记平台中公开的相关专利信息,包括专利名称、专利号、相关的权利要求等;(二)中国上市药品专利信息登记平台中公开的申请注册药品的相关信息,包括药品名称、药品类型、注册类别以及申请注册药品与所涉及的上市药品之间的对应关系等;(三)药品上市许可申请人依据《药品专利纠纷早期解决机制实施办法(试行)》作出的四类声明及声明依据。

药品上市许可申请人提起诉讼时可参照上述内容提交用以证明其具体诉讼请求和事实理由的证据材料。

第六条【提起诉讼的期限】

专利权人或者利害关系人在国家药品审评机构公开药品上市许可申请之日起45日内不提起诉讼的,药品上市许可申请人可以提起诉讼。药品上市许可申请人提起诉讼时应提交专利权人或者利害关系人45日内未提起诉讼的相关证据材料,无法提交相关证据材料的,可提交相关说明。

第七条【公证认证手续】

原告是外国人、外国企业或组织的,应在立案时提交符合规定的主体公证认证文件。原告是在内地没有住所的香港、澳门居民、企业或组织的,应在立案时提交符合规定的公证、并经转递的主体证明文件。原告是在内地没有住所的台湾居民、企业或组织的,应在立案时提交符合规定的公证、并经中国或北京公证协会认证的主体证明文件。

第八条【其他】

其他立案要求,依照相关法律、法规、规定执行。

北京知识产权法院关于申请注册的药品相关的专利权纠纷民事案件立案指引(试行)的说明

为便于更好地理解《北京知识产权法院关于申请注册的药品相关的专利权纠纷民事案件立案指引(试行)》,现就该指引相关内容说明如下:

一、关于专利被许可人应提交的主体资格证明材料

《最高人民法院关于审查知识产权纠纷行为保全案件适用法律若干问题的规定》第二条规定,知识产权许可合同的被许可人申请诉前责令停止侵害知识产权行为的,独占许可合同的被许可人可以单独向人民法院提出申请;排他许可合同的被许可人在权利人不申请的情况下,可以单独提出申请;普通许可合同的被许可人经权利人明确授权以自己的名义起诉的,可以单独提出申请。参照上述规定,在申请注册的药品相关的专利权纠纷民事案件中,专利被许可人提起诉讼的,应提交符合上述规定内容的主体资格证明材料。

二、关于被告的问题

考虑到申请注册的药品相关的专利权纠纷民事案件与确认不侵害知识产权纠纷案件的共性特征,根据确认不侵害知识产权纠纷案件在先生效文书中确立的原则,在申请注册的药品相关的专利权纠纷民事案件中,药品上市许可申请人作为原告提起诉讼的,应以专利权人为被告。

三、关于涉外及涉港澳台主体的公证认证手续问题

根据北京市高级人民法院《关于行政审判适用法律问题的解答(三)》的规定,律师事务所或者有关代理机构受外国自然人、法人的委托代理行政诉讼事宜,律师事务所或者有关代理机构在法律规定的起诉期限内向法院递交起诉状和委托人签署的委托书的传真件或者电子邮件等初步证明,并在起诉后三个月内向受案法院递交委托书的公证、认证文件的,可以视为没有超过起诉期限。申请注册药品相关专利权纠纷属于民事诉讼,不适用上述解答意见。因此,原告为涉外及涉港澳台主体的,应在立案申请时提交完整的公证认证文件。

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.

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