2020 年 10 月 25 号

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答复：《药品专利纠纷早期解决机制实施办法（试行）（征求意见稿）》

尊敬的国家药品监督管理局和国家知识产权局:

美国知识产权所有者协会 （IPO） 非常感谢有机会对 2020 年 9 月 11 日公布的《药品专利纠纷早期解决机制实施办法（试行）（征求意见稿）》（以下简称《实施办法草稿》）有所回应。

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IPO 对《实施办法草稿》中提出的保护药品专利权人合法权益、鼓励新药研究和促进高水平仿制药发展、建立药品专利纠纷早期解决机制提出感谢。我们注意到，《实施办法草稿》似乎是针对最近的《美利坚合众国和中华人民共和国第一阶段经贸协议》（"第一阶段协议"）中有关早期解决专利纠纷机制的某些条款，如第 1.11 条（"早期解决专利纠纷的有效机制"）。IPO 认为，此次征求意见是对《第一阶段协议》中两国加强知识产权保护合作协议的重要和有益的落实。我们希望我们的以下意见能在《实施办法草稿》定稿过程中有所帮助。

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总评

IPO 认可《实施办法草稿》中为寻求尽早解决制药领域专利纠纷的机制而做出的努力。但是，请考虑以下我们为确保该《实施办法草稿》提供专利权人公平有效的机制来解决与通用/后续公司的专利纠纷的意见，我们建议一系列的建议让《实施办法草稿》为创新者的专利权提供有意义的保护。

IPO 注意到，与化学药品（小分子，通常使用<1000 道尔顿的药物）相比，本实施办法对生物制剂提供了不同的待遇（例如，可以在暂缓条款中列出的专利）。但是，《第一阶段协议》第 1.11 条并未在小分子和生物制剂之间进行这种区分。IPO 的想法是，根据《实施办法草稿》，在生物制剂和化学药品之间不应有区别对待。

此外，在中国越来越需要引入注册数据保护，尤其是考虑到第 11 条提议的第一个为期 12 个月的市场独占权，以使第一家仿制药公司成功挑战专利有效性并获得市场认可。如果没有法律规定的注册数据保护，规定从创新药物的市场销售许可起至少四年内不得再提交后续申请，我们担心《实施办法草稿》未能为创新者提供足够的保护。这些创新者在开发此类数据时花费大量资源，并在开发和批准药物的过程中承担风险。

以下是有关《实施办法草稿》的其他可能会严重影响有关人员的权利的问题。

第 3 条和第 4 条

IPO 建议将第 3 条和第 4 条合并，并在获得药品上市许可后注册专利信息。药品申请获得批准后，某些信息（例如适应症）与提交时的内容相比可能会有所不同。建议注册平台仅注册市售药品的相关专利信息，以减轻管理负担，并避免信息中的不一致，因为不一致可能会对仿制药申请人提出专利声明造成潜在的不确定性。我们还建议将有关期间从 30 天增加到 60 天，以留出更多时间，尤其是对于外国单位而言。因此，我们建议进行以下修改：

> ***第四条【信息管理】药品上市许可持有人（“ MAH”）自收到上市批准之日起 60 天内应注册药品名称、相关专利号、专利类型、专利状态、专利权人、MAH、专利保护到期日、通信地址、联系人，联系方式和其他内容。 MAH 对提交的专利信息的真实性，准确性和完整性负责。***
>
> *上市批准后的任意时间取得额外专利权的，可在公告授予专利权之日起 60 日内在中国上市药品专利信息登记平台登记专利信息，并向国家药品审评机构补充提交专利信息。已登记的药品专利信息发生变更时，药品上市许可持有人应当在变更生效后 60 日内在中国上市药品专利信息登记平台进行变更登记。*

此外，IPO 建议为那些已经在市场上销售并且专利符合《实施办法草稿》制定时规定的创新药物增加过渡期，以便专利权人或市场授权/批准持有人（“MAH”）可以在本办法制定的规定时间内提交专利信息。

第 5 和第 12 条

第 5 条似乎仅适用于化学药品。对于生物制剂，第 12 条似乎仅限于涵盖序列表的专利。 IPO 建议对化学药品和生物药品（包括药物制剂）应用更广泛的保护，如对第 5 条的以下修订所示：

> **第五条 【平台登记专利类型】***化学或生物药品 MAH 可在中国上市药品专利信息登记平台登记药物活性成分化合物专利、含活性成分的药物组合物或制剂专利、活性成分化合物的制造方法、医药用途专利。*

替代地（尽管并非优选，因为这将是多余的并且不够简洁），第 12 条可以扩展为包括活性生物制剂，包含生物制剂的药物组合物或制剂，制造活性生物制剂的方法以及除序列表以外的药物用途的专利，例如如下所示：

> **第十二条【分类处理】**生物制品、中药 MAH，按照本办法第二、三、四、五、六、七条，进行相关专利信息登记、声明等。生物制品可登记涉及活性生物制剂、包含生物制剂的药物组合物或制剂、医药用途、制造活性生物制剂的方法和序列结构专利，中药可登记中药组合物专利、中药提取物专利、医药用途专利。

第 6 和第 7 条

IPO 担心《实施办法草稿》没有建立有效的制度来通知专利和其他权利人侵权的仿制药申请。相反，该实施办法似乎为中国上市药品专利信息注册平台（“ PIRPAD”）提供了一个潜在的混乱系统，可能在仿制药申请人、专利权人、和 NMPA 之间引起更多混乱和争议。

《第一阶段协议》在 1.11（a）条中规定，中国应提供“**向专利持有人**，被许可人或市场批准持有人发出通知的系统，该另一人正在寻求在适用专利期限内推销该产品声明批准的产品或其批准的使用方法。”（以粗体强调）。相反地， 实施办法中提出的程序使专利权人有责任监视数据库。因触发点发出与仿制药申请人，请考虑仿制药申请人除了发布外，应该还需要在声明后通知 MAH（并证明已通知 MAH）。

IPO 建议采用以下机制：

- 修改第 6 条，要求提交仿制药品申请并声明具有第 6 条第 II 到 IV 类声明的申请人，在向 NMPA 提交此类声明时，将此类声明通知所引用产品的专利权人、被许可人或持有人。

- 如下所示，对的第 7 条的 45 天的期间进行修订以从收到第 6 条的声明通知开始计算。 如果仿制药申请人在提交专利时向专利权人发出通知，则 45 天的

时间可能足够。 但是，对于仅依靠自己对注册簿进行监控者而言，这还不够且对此方不利 。 如果需要创新者来监视注册，则应延长时间窗口。

> *“专利权人或者利害关系人对专利声明、声明依据有异议的，可以自国家药品审评机构公示药品上市许可申请之日起或从 ANDA 申请人处收到声明通知起（以较晚者为准）45 日内，就申请上市药品的相关技术方案是否落入相关专利权保护范围向人民法院提起诉讼或者向国务院专利行政部门申请行政裁决。”*

- 请提供有关专利权人不提起诉讼的影响的说明。例如，是否会使专利权人以后不能再主张专利权？在 45 天的窗口期结束后的未决期间，专利权人是否会被阻止提起诉讼？这是否会导致批准不属于专利权的保护范围内？

第 8 条

如上所述，我们建议将第 8 条扩展为包括生物制剂。 IPO 建议进行以下修订，以为创新公司解决与通用/后续公司的专利纠纷提供更公平有效的机制:

- 将等待期从 9 个月延长至 24 个月，以便有足够的时间来解决专利纠纷，包括对行政裁决进行司法审评，除非在此之前解决了此案。 《第一阶段协议》在 1.11(b) 中指出中国“为这样的专利持有人提供足够的时间和机会在涉嫌侵权的产品上市之前寻求可用的补救措施”。尽管从理论上讲 9 个月的窗口期足以满足 CNIPA 的行政裁定，但实际上大多数时候还不够。 而且，该窗口期通常不足以进行司法裁定或司法审评。
- 如果相关的司法（侵权）和/或行政（无效）程序被中止，则同时中止等待期。

第 9 条和第 10 条

如上所述，我们建议将第 9 条和第 10 条扩展为包括生物制剂。

关于第 10 条，我们建议删除第（IV）款。 根据第（IV）款，如果未发布法院或行政裁决，则药品批准申请将照常进行。 但是，MAH 不应因法院的延误而受到处罚，因此将等待期从 9 个月延长至 24 个月很重要。

第 11 条

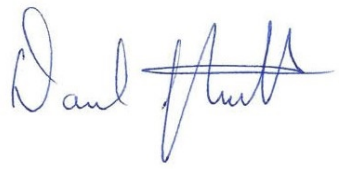
IPO 要求澄清第 11 条是仅基于有效性还是基于申请人的非侵权性而仅限于挑战专利。 IPO 建议仅限于成功使有争议专利无效的首个挑战者。

此外，为确保创新者和仿制药/仿制药公司建立一种公平的机制，在中国没有监管数据保护的情况下，IPO 建议增加一条规定，即自创新药上市许可后至少四年内不得再提交后续申请。 或者，IPO 建议中国同时实施公平、有意义的注册数据规定。

感谢国家药品监督管理局和国家知识产权局给我们这次发表意见的机会，我们欢迎进一步的对话和提供补充意见的机会。

IPO 随信附上本信函的翻译。

此致



Daniel J. Staudt
美国知识产权所有人协会主席

附件：《药品专利纠纷早期解决机制实施办法（试行）（征求意见稿）》的反馈意见—英文版

25 October 2020

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Via Email: swzpc@nmpa.gov.cn

Re: Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial) (Draft for Solicitation of Comments)

Dear National Medical Products Administration and China National Intellectual Property Administration:

The Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the request for comments on the *Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)(Draft for Solicitation of Comments)* ("Draft Measures") published on 11 September 2020.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes 175 companies and close to 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries.

IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

IPO appreciates the objectives stated in the Draft Measures to protect the legitimate rights and interests of drug patent holders, encourage new drug research and promote the development of high-level generic drugs, and establish an early resolution mechanism for drug patent disputes. We note that the Draft Measures appear to be directed to certain provisions of the recent Phase One Economic and

Trade Agreement between the United States of America and the People's Republic of China ("Phase One Agreement") relating to mechanisms for early resolution of patent disputes, such as Article 1.11 ("Effective Mechanism for Early Resolution of Patent Disputes"). IPO views this invitation for comments as an important and useful implementation of the two countries' agreement to strengthen their cooperation regarding intellectual property protection, as memorialized in the Phase One Agreement. We hope that our comments below will be helpful during the process of finalizing the Draft Measures.

General Comments

IPO recognizes the efforts undertaken in the Draft Measures to seek to provide a mechanism for early resolution of patent disputes in the pharmaceutical arena. However, please consider the following comments to the Draft Measures to ensure patent owners are provided a fair and effective mechanism to resolve patent disputes with generic/follow-on companies and we suggest a number of revisions to enable the Draft Measures to provide meaningful protection for innovators' patent rights.

IPO notes that the Draft Measures provide different treatment (e.g., patents that could be listed under the stay provisions) for biologics compared to chemical (small molecule, generally with <1000 Daltons) drugs. However, Article 1.11 of the Phase One Agreement makes no such distinction between small molecules and biologics. IPO believes there should not be a distinction in treatment between biologics and chemicals under the Draft Measures.

There is also an increasing need to introduce regulatory data protection in China, especially given the 12-month market exclusivity proposed in Article 11 for the first generic company to successfully challenge patent validity and obtain market approval. Without regulatory data protection in the laws specifying that no follow-on applications shall be filed within a period of at least 4 years from marketing approval of the innovator drug, we are concerned that the Draft Measures provide inadequate protection to innovators who expend significant resources in developing such data and undertake risks in the path towards drug development and approval.

Below are some additional comments for your consideration regarding the text of the Draft Measures that could significantly impact the rights of those involved.

Articles 3 and 4

IPO recommends combining Article 3 and 4, and registering the patent information after receiving the drug marketing approval. After the drug application is approved, some information (such as indications) may be different from the content at the time of submission. It is recommended that the registration platform only register the relevant patent information of the marketed drug to reduce administrative burden and avoid inconsistencies in the information which may cause potential uncertainty for generic drug applicants in filing a patent declaration. We also suggest increasing the time period from 30 days to 60 days to allow more time, particularly for foreign entities. We therefore propose the following revisions:

> *Article 4 [Information Management]* ***Within 60 days from the date of receiving marketing approval, the Marketing Authorization Holder ("MAH") shall register the drug name, relevant patent number, patent type, patent status, patentee, MAH, expiration date of patent***

> ***protection, correspondence address, contact person, contact information and other contents by itself. The MAH shall be responsible for the authenticity, accuracy and completeness of the patent information submitted.***
>
> *~~During the drug review period~~* ***Any time after marketing approval****, if ~~the applicant obtains~~ the* ***additional*** *patent right* ***is obtained****,* ***the MAH*** *can register the patent information on the Chinese listed drug patent information registration platform within ~~30~~* ***60*** *days from the date of the announcement of the grant of the patent right, and supplement it to the national drug review agency submit patent information. When there is a change in the registered drug patent information, the ~~applicant or the~~ drug marketing authorization holder shall register the change in the Chinese listed drug patent information registration platform within ~~30~~* ***60*** *days after the change takes effect.*

In addition, IPO recommends adding a transition period for those innovative drugs already on the market and for which the patents satisfy the provisions at the time the Measures are enacted, so that the patentee or the market authorization/approval holder ("MAH") may submit the patent information within a set period of time of the enactment of these Measures.

Articles 5 and 12

Article 5 seems to apply to chemical drugs only. For biologics, Article 12 appears to be limited to patents covering sequence listings. IPO recommends applying broader protection for chemical drugs and biologics, including pharmaceutical formulations, as shown in the following revisions to Article 5:

> *Article 5 [Platform Registration Patent Type] ~~When a~~* ***A*** *chemical* ***or biologic*** *drug ~~registration applicant submits a drug marketing authorization application, it~~* ***MAH*** *may register a patent for active ingredient compounds, a patent for a pharmaceutical composition* ***or formulation*** *containing an active ingredient,* ***method of manufacturing of the active ingredient compounds*** *and a patent for medical uses on the China Listed Drug Patent Information Registration Platform.*

Alternatively (though less preferred as this would be redundant and less concise), Article 12 can be expanded to include patents covering active biologics, pharmaceutical composition or formulation containing biologics, method of manufacturing the active biologics and pharmaceutical use in addition to sequence listings, as shown below:

> *Article 12 [Classification Processing] ~~Applicants for marketing registration~~* ***MAH*** *of biological products and traditional Chinese medicines shall register and declare relevant patent information in accordance with Articles 2, 3, 4,* ***5,*** *6, and 7 of these Measures. Biological products can be registered for* ***patents covering active biologics, pharmaceutical composition or formulation containing biologics, medical uses, method of manufacturing the active biologics and*** *sequence structure, and Chinese medicines can be registered for patents for traditional Chinese medicine composition, traditional Chinese medicine extracts, and medical uses.*

Articles 6 and 7

IPO is concerned that the Draft Measures do not create an effective system for notifying patent and other rights holders of infringing generic drug applications. Rather, the system of Patent Information Registration Platform for Listed Drugs in China ("PIRPAD") that the Draft Measures would create could cause confusion and additional disputes between generic drug applicants, patent rights holders, and NMPA.

The Phase One Agreement states in Art. 1.11(a) that China shall provide "**a system to provide notice to a patent holder**, licensee, or holder of marketing approval, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use." (emphasis added in bold). The process proposed in the Draft Measures makes it the responsibility of the patentee to monitor the databases. Because the triggering event will be emanating from the generic drug applicants, please consider that the generic drug applicants should notify the MAH (and certify that the MAH has been notified) upon making a declaration, in addition to the publication.

IPO suggests that the following mechanisms be adopted:

- Revise Article 6 to require applicants filing Generic Drug Applications with declarations certifying Categories II to IV of Article 6 **to notify** patentees, licensees, or holders of the marketing approval of the referenced product of such declarations at the time of submission to NMPA.

- Revise Article 7 such that the 45-day window would start from the receipt of the notification of the declarations pursuant to Article 6, as shown below. The 45-day window may be sufficient time if the patentee is provided notice by the generic drug applicant upon filing. However, it would not be sufficient for and would prejudice a party who have to rely on their own monitoring of the register. The time window should be extended if innovators are required to monitor the register.

> *"The patentee or any interested party who have objections to the patent declaration(s) and the declaration basis may, within 45 days from the date when the national drug evaluation institution makes public the application for the drug marketing approval* ***or from receiving the notification of declarations from the ANDA applicators, whichever is later****, file a lawsuit before People's court or apply to the patent administration department under the State Council for an administrative ruling, regarding whether the relevant technical solutions of the drug applied for market approval fall within the protection scope of the patent rights."*

- Provide clarification on what the effect is if the patentee does not file a lawsuit. For example, will this preclude the patentee from patent assertion at a later date? Will the patentee be prevented from filing a lawsuit during the pendency of the application after the 45-day window? Will this have an effect that the approval does not fall within the protected scope of the patent right?

Article 8

As explained above, we recommend that Article 8 be expanded to include biologics. IPO suggests the following revisions to provide a more fair and effective mechanism for innovator companies to resolve patent disputes with generic/follow-on companies:

- Increase the stay period from 9 months to 24 months to allow sufficient time to resolve patent disputes including judicial review of administrative rulings, unless the case is resolved prior to that time. The Phase One Agreement requires in Article 1.11(b) that China provide "adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies." While the 9-month window may theoretically be enough for administrative rulings by CNIPA, in practice most of the time it is not sufficient. Moreover, this window will generally not be enough for judicial ruling or juridical review.
- Suspend the stay period in parallel if the related judicial (infringement) and/or administrative (invalidation) proceeding is suspended.

Articles 9 and 10

As explained above, we recommend that Articles 9 and 10 be expanded to include biologics.

With respect to Article 10, we recommend deleting paragraph (IV). According to paragraph (IV), the drug approval application will proceed as normal if the court or administration ruling is not issued. However, the MAH should not be penalized for delays by the court, and thus it is important to increase the stay period from 9 months to 24 months.

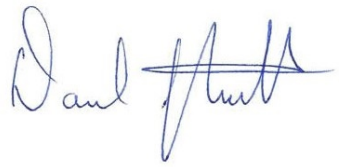
Article 11

IPO seeks clarification as to whether Article 11 is limited to challenging patents based on validity only, or also on the basis of an applicant's non-infringement. IPO recommends that it should be limited to the first challenger successfully invalidating the patent at issue.

Moreover, to ensure a fair mechanism for both innovators and generic/follow-on companies, where there is no regulatory data protection in China, IPO suggests adding a provision that no follow-on applications shall be filed within a period of at least 4 years from marketing approval of the innovator drug. Alternatively, IPO recommends that China implement fair and meaningful regulatory data provisions for the same time period.

IPO thanks the National Medical Products Administration and China National Intellectual Property Administration for this opportunity to comment, and welcomes further dialogue and opportunity to provide additional comments. IPO attaches this letter as translated herewith.

Sincerely,



Daniel J. Staudt
President

Attachment