2020 年 12 月 13 号

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***主题：*《关于审理涉药品上市审评审批专利民事案件适用法律若干问题的规定》（征求意见稿）反馈意见**

尊敬的胡庭长您好：

美国知识产权所有者协会 （IPO） 非常感谢有机会对 2020 年 10 月 29 日公布的《关于审理涉药品上市审评审批专利民事案件适用法律若干问题的规定》（征求意见稿）（以下简称《规定》）提交意见的机会。

IPO 是一个代表所有行业和技术领域中拥有知识产权或对知识产权感兴趣的公司和个人的国际贸易协会。 IPO 的成员包括 175 家公司和近 12,000 名个人，他们通过其公司或作为发明人、作者、律师事务所或律师成员参与协会。IPO 的成员遍布 30 多个国家。

IPO 倡导有效和实惠的知识产权所有权，并提供广泛的服务，包括支持成员在立法和国际问题上的利益；分析当前的知识产权问题；提供信息和教育服务；以及向公众传播有关知识产权重要性的信息。

IPO 盛赞最高人民法院在促进创新方面所做的努力。我们很高兴地看到法院、国家药品监督管理局、国家知识产权局都在致力于为中国建立一个新的药物专利链接制度。我们也注意到《规定》看上去对应于《中华人民共和国政府和美利坚合众国政府经济贸易协议》（以下简称《第一阶段协议》）中有关早期解决专利纠纷机制的某些条款，例如第 1.11 条专利纠纷早期解决的有效机制。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。我们希望以下意见能在《规定》定稿过程中有所帮助。

综合意见

由于药物专利链接制度在中国是全新的，大家希望《规定》对这个制度在实际中公平有效的落实提供指导。一个公平而有效的中国药物专利链接制度不仅需要在仿制药厂和原研药厂的利益中找到平衡，也需要法院和各有关政府部门保持一致性。对相关法律法规的改进必须同时进行，以保

证相关参与人能够对方案进行完整的、全方位的考量。此外，如《规定》这样的法规和司法解释应该与更高一级的法律法规一致。正如以下详述所说，IPO 希望《规定》与最近颁布的《中华人民共和国专利法》第四次修改以及国家药监局、国家知识产权局在 2020 年 9 月 11 日发布的《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》）都能意义明确、与自身条款一致并相互一致。

首先，IPO注意到《规定》没有说明法院作出判决的时间限定。《实施办法草稿》中规定了对仿制药注册申请自法院立案后 9 个月的行政审批等待期，而《规定》中却没有相关的期限。如果在 9 个月内法院未作出生效判决，药监局会将仿制药申请转入行政审批环节。由于在等待期内技术审评不停止，有可能在诉讼结束前药监局就会批准仿制药注册申请。而在那之后，即使北京知识产权法院判定仿制药厂侵权，药监局也不会撤回批准，从而使得专利链接制度形同虚设。

IPO也希望得到对专利法第七十六条下规定的诉讼种类的澄清。《规定》中某些条款似乎暗示了在专利法第七十六条下对可能侵权产品进入市场前解决专利纠纷与传统的专利侵权案有所不同。我们不清楚的是，当事人是可以向法院或知识产权局提出专利侵权或不侵权认定，可以向知识产权局提出专利全无效宣告申请，还是可以向法院或知识产权局提出其它类型的诉讼（例如一种新的准侵权诉讼或者准不侵权诉讼）。一个高效的早期专利纠纷解决机制必须对纠纷如何早期解决以及管辖权做出清晰的指导。

最后，我们希望最高人民法院在与其它政府机构协同建立公平有效的专利链接制度时对以下两个方面作出额外关注：

1. 专利法第七十六条针对的是药品上市许可。随着现有以及可以预见到的技术进步，药品已经不限于小分子化合物。可以治病救人的有效药物也包括了生物制剂。而且除了化合物成分以外，药物组合或制剂、活性成分的制备方法、以及特定医学用途也可能起到重要作用。这些药物的专利往往是大量研发工作得到的结果，而且不仅仅限于化合物成分。因此，无论其它政府机构如何定义药品，对专利法第七十六条的司法解释应当反映出药品的广泛性。

2. 法院应该给予当事人合理的时间来收集证据。《第一阶段协议》在第 1.11 条一（一）中规定，中国应 “规定制度，以通知专利权人、被许可人或上市许可持有人，上述其他人正在已获批产品或其获批使用方法所适用的专利有效期内寻求上市该产品”。然而，国家药监局和国家知识产权局《实施办法草稿》中提出的流程并没有要求仿制药品申请人作出相关专利声明时通知已上市药品许可持有人。反而是专利权人或者利害关系人对专利声明有异议的，需要在国家药监局公示药品上市许可申请之日起 45 日提出诉讼。在没有得到通知的情况下，专利权人或者利害关系人可能在这 45 天期限内只有非常少的时间可以为诉讼做准备。因此，法院对初步证据充分性的判断应当考虑到专利权人或者利害关系人是否及何时得到通知这一因素。

第二、四、十八条

《规定》第二条对专利法第七十六条中的“专利”的定义非常狭窄，IPO为此感到担忧。这个定义直接基于中国上市药品专利信息注册平台登记的专利，因而完全依赖于中国上市药品专利信息注册平台的定义和建立。

如上文综合意见中所述，专利法第七十六条中的“专利”和“药品”应当有广泛的定义，才能反映制药行业的最新技术水平。我们虽然希望国家药监局明确提供这样广泛的定义，但是目前国家药监局和国家知识产权局《实施办法草稿》中对于可在中国上市药品专利信息注册平台登记的专利定义过于狭窄而不合理。 IPO 此前已向国家药监局和国家知识产权局提交了有关扩充登记专利种类的意见。但是，如果中国上市药品专利信息注册平台最终并未涵盖所有相关专利，我们希望对“专利”适当的司法解释能反映正确的立法目的，亦即对“专利”广泛的定义。

具体而言，我们注意到，在专利法草案的前一版，即由全国人民代表大会于2020年 7 月 3 日发布的《中华人民共和国专利法修正案（草案二次审议稿）》中，第七十五条增加了有关专利链接的条款，该条款规定了提出诉讼的专利限于中国上市药品专利信息登记平台登载的相关专利。然而在 2020 年 10 月 17 日发布的《全国人民代表大会常务委员会关于修改<中华人民共和国专利法>的决定》中，该限制被取消。专利法第七十六条中提出“申请注册的药品相关的专利权”，而完全没有提及中国上市药品专利信息登记平台。由此可见，专利法的立法目的是不将第七十六条中的专利限制为在中国上市药品专利信息登记平台上登记的专利。因此，法院也不应作出这种限制。

IPO建议对《规定》第二条进行修订，以澄清“药品”一词既包括化学产品也包括生物制剂，并且将“申请注册的药品相关的专利权”定义为与已上市药品（包括化学与生物制剂）有关的专利权，这些专利包括已上市药品的活性成分、药物组合或制剂、活性成分的制备方法、以及已批准的医学用途。

我们还建议删除《规定》第四条，并修改第十八条使其仅适用于涉及在中国上市药品专利信息登记平台上登记过的专利的案件。

第三条

如上文综合意见中所述，法院应该给予当事人合理的时间来为诉讼做准备，尤其是在已上市药品许可持有人没有得到仿制药品申请人作出相关专利声明通知的情况下。《规定》第三条要求在起诉时提交关于申请注册的药品技术方案是否落入相关专利权保护范围的初步证据。 IPO 建议在第三条中添加条款，以澄清法院在评估初步证据的充分性时应考虑当事人何时收到仿制药品申请提交的通知。

第七条

为使含义明确，我们建议在将“人民法院一般不予支持”中的“一般”一词删除。

第八条

《规定》第八条的第二部分规定，国务院专利行政部门宣告当事人提起专利法第七十六条所称诉讼依据的权利要求无效，或者一审行政判决认定该权利要求具有应当被宣告无效的情形的，人民法院可以根据药品上市许可申请人的请求，判决确认申请注册的药品相关技术方案未落入相关专利权保护范围。我们不清楚法院判定相关技术方案未落入相关专利权保护范围的法律依据是什么。 IPO 建议删除第八条的这一部分，或着写明判定所用的法律依据。

第九条

《规定》第九条的第一段中规定，药品上市许可申请人在专利法第七十六条所称诉讼中存在不视为侵犯专利权的法定情形的，人民法院经审查成立，可以根据药品上市许可申请人的请求，判决确认申请注册的药品相关技术方案未落入相关专利权保护范围。我们认为不视为侵犯专利权的法定情形是由专利法第七十五条规定的。《规定》所针对的是专利法第七十六条规定的涉及药品上市审评审批的专利案件，对专利法第七十五条进行解释既无必要也不合适。因此，我们建议将“或者存在不视为侵犯专利权的法定情形的”从第一段中删除。

第九条的第二段针对的是药品上市许可申请人答辩主张相关专利权明显属于应当被宣告无效的情形。虽然本段没有给予法院判决专利权无效的权力，但似乎暗示了法院可以根据仿制药上市许可申请人的答辩来审理专利权有效性。这样一来，同一个专利就有可能面对两个平行的专利权有效性案件，使得专利权利人处于不公平的弱势。因此，我们建议将此段删除。

第十二条

IPO 对《规定》第十二条表示欢迎，因为它确认了部分侵权的可能性，这有可能会影响到仿制药上市许可申请的批准。为了表明在裁判主文中分别作出认定的目的，我们建议在“人民法院应当在裁判主文中分别作出认定”之前加入“为了帮助国家药品审评机构做出相应处理，”。

第十三条

《规定》第十三条针对的是药品上市许可申请人向人民法院提交的申请注册的药品相关技术方案，与其向国家药品审评机构申报的技术资料明显不符，足以影响案件正常审理的情形。其所依照的民事诉讼法第一百一十一条规定人民法院对此行为的单位，可以对其主要负责人或者直接责任人员予以罚款、拘留；构成犯罪的，依法追究刑事责任。然而，民事诉讼法第一百一十一条并没有规定这种提交明显不符资料的行为会对专利诉讼有何影响。IPO 建议根据《最高人民法院关于知识产权民事诉讼证据的若干规定》第二十五条的内容来修订《规定》第十三条，亦即无正当理由提交虚假证据的，人民法院可以推定对方当事人就该证据所涉证明事项的主张成立。

第十五条

《规定》第十五条规定，如果人民法院在申请注册的药品被依法批准上市后作出认定该药品相关技术方案落入相关专利权保护范围的，专利权人或者利害关系人可以针对当事人实施的专利侵权行为另行提起侵害专利权诉讼。IPO 指出，在这种情况下，如果专利权人或者利害关系人不能得到禁令救济，药物专利链接制度将会失去意义。因此，我们建议在第十五条中加入以下条款作为第二段：

如专利权人或者利害关系人在本条前款的侵害专利权诉讼中申请了禁令救济，并以前款中认定该申请注册的药品相关技术方案落入相关专利权保护范围的人民法院生效裁判作为依据，要求禁止或提前制止药品上市许可申请人为生产经营目的制造、使用、许诺销售、销售、进口专利产品的行为的，人民法院应予支持。

第十七条

《规定》第十七条看似与专利法第二十条中的诚实信用原则和不得滥用专利权损害公共利益或者他人合法权益相关。IPO 在专利法起草过程中的不同阶段都提交过意见，要求对何为“滥用专利权”作出澄清和指导。同样在这里，IPO 恳请最高人民法院将“滥用专利权”与已知的清晰的法律概念联系起来，以给出明确的定义。我们非常担心，如果没有这样一个明确定义，《规定》第十七条会使行使专利诉讼权的专利权人或者利害关系人负担过重的法律责任，并可能面对不可预期的风险。

最低限度，IPO建议，应当澄清“全部诉讼请求均未得到支持”本身并不应成为请求赔偿损失以及诉讼合理开支的唯一理由。举例而言，当事人有可能因受到时间限制或者因无法得到所需信息而败诉。在诉讼中败诉这一事实本身并不说明专利权被滥用。

因此，我们建议将“或者全部诉讼请求均未得到支持”从第十七条中删除。我们也建议，如果不能明确地定义“滥用专利权”，应将第十七条完全删除。

感谢最高人民法院给 IPO 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。随信附上本信函的英文翻译版本。

此致

Daniel J. Staudt
美国知识产权所有人协会主席

附件：IPO 协会对《关于审理涉药品上市审评审批专利民事案件适用法律若干问题的规定》（征求意见稿）的反馈意见 - 英文版

13 December 2020

Hu Shihao, Chief Judge
Civil Adjudication Tribunal No. 3 (IPR Division)
The Supreme People's Court of the People's Republic of China
27 Dongjiaomin Alley
Dongcheng District
Beijing 100745
P.R.China

Via Email: patentlink@163.com

Re: The Supreme People's Court Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval (Draft for Solicitation of Comments)

Dear Chief Judge Hu:

The Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the request for comments on the *Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval (Draft for Solicitation of Comments)* ("Draft Provisions") published on 29 October 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 commends the Supreme People's Court for its efforts in promoting innovation. We are glad to see that the courts, the National Medical Products Administration ("NMPA"), and the China National Intellectual Property Administration ("CNIPA") are all working on establishing the new patent linkage system in China. We note that the Draft Provisions appear to be directed to certain provisions of the 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 aspect of 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 Provisions.

General Comments

As the patent linkage provisions are new for China, it is hoped that the Draft Provisions will provide guidance on how the system will be implemented fairly and effectively in practice. A fair and effective linkage system for China will not only need to balance the interests of generics and innovators, but also will need consistency between the courts and the range of concerned administrative agencies. Synchronous reforms to the relevant laws and regulations are necessary to enable stakeholders to consider the proposed scheme fully and holistically. Furthermore, rules and judicial interpretations such as the Draft Provisions should be harmonized with higher level laws and regulations. As detailed below, IPO would like to obtain clarifications and encourage consistency within and across the Draft Provisions and with the recently enacted Fourth Amendment to the Patent Law and NMPA/CNIPA's Draft Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes ("Draft Measures") published on 11 September 2020.

First, IPO notes the absence of a time limit for the court to issue a decision in the Draft Provisions. The current version of the NMPA/CNIPA's Draft Measures has a 9-month time limit for litigation to conclude, which the Draft Provisions do not. Failure to conclude the litigation within 9 months allows the NMPA to end the moratorium on approval. As the NMPA does not suspend evaluation during the moratorium, it is possible that the NMPA could issue marketing approval before the litigation concludes. The NMPA will not revoke marketing approval even if the Beijing IP Court rules against the generic manufacturer, rendering the patent linkage litigation moot.

IPO would also like to get clarification on the types of actions that can be pursued under Article 76 of the Patent Law. Several articles in the Draft Provisions seem to suggest that the action established under Article 76 of the Patent Law to resolve a patent dispute before a potentially infringing product enters the market may be distinct from a traditional infringement action. It is unclear whether parties can pursue an infringement or declaration of non-infringement action in court or before CNIPA, and an invalidity action before CNIPA, or something else (a new quasi-infringement action and quasi-non-infringement action), which can be brought either in court or before CNIPA. It is critical to provide clear guidance about how patent disputes can be resolved early, and in which venues, to ensure an effective early patent dispute resolution framework.

Finally, there are also two areas we are hoping that the SPC can pay special attention to in its effort of coordinating with other government agencies to build a fair and effective linkage system:

1. Article 76 of the Patent Law is directed to drug marketing applications. With the current and foreseeable technology advancement, drugs are no longer limited to small molecule chemical compounds. Effective medicines that are disease-curing and life-saving can include biologics as well. Besides chemical compositions, pharmaceutical composition or formulation, method of manufacturing of the active ingredient, or specific medical use may also play an important role. Therefore, the

patents underlying these drugs, which typically are the results of significant research and development work, may not be limited to chemical compositions either. Accordingly, any judicial interpretation of Article 76 of the Patent Law should reflect such a broad coverage of drugs, regardless of how "drugs" may be defined by other government agencies.

2. The courts should allow relevant parties reasonable time to gather evidence. The Phase One Agreement in Art. 1.11(a) sets out 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." However, the process proposed in the current version of the NMPA/CNIPA's Draft Measures does not require a generic drug applicant to notify the Marketing Authorization Holder when it makes a patent statement in its generic drug application. Rather, the patentee or interested party opposing such a patent statement is given a 45-day window from the date when NMPA makes the generic drug application public to bring an action. Without notification, the patentee or interested party may have very limited time to prepare for a litigation by the end of the 45-day window. Accordingly, the courts should take the notification factor into account when considering the sufficiency of the initial evidence.

Articles 2, 4, and 18

IPO is concerned about the narrow interpretation in Article 2 of the Draft Provisions of "patents" in Article 76 of the Patent Law. Because this interpretation is directly based on patents registered in the Patent Information Registration Platform for Listed Drugs in China ("PIRPAD"), it relies solely on the appropriate definition and establishment of PIRPAD.

As explained above in General Comments, "drugs" as well as "patents" in Article 76 of the Patent Law should be interpreted broadly in order to reflect the current state of the art in the pharmaceutical industry. While we would like to see a broad definition be clearly provided by NMPA, the current version of the NMPA/CNIPA's Draft Measures is unreasonably narrow in terms of what type of patents can be registered in PIRPAD. IPO previously submitted comments to NMPA/CNIPA regarding broadening the types of patents for registration. However, in the case that PIRPAD does not cover all of the relevant patents, we would like to see a proper judicial interpretation of the term "patents" to reflect the legislative intent of broad coverage.

Specifically, we have noted that, in the previous version of the draft Patent Law, Amended Patent Law (Draft for Second Review) (published by the National People's Congress on 3 July 2020), Article 75 was amended to include a paragraph relating to patent linkage. In that version, the patents based on which action can be brought were limited to those registered in PIRPAD. In the current Patent Law, as amended on 17 October 2020, however, that limitation was eliminated. Article 76 of the Patent Law refers to "patent rights relevant to drug application," but does not mention PIRPAD at all. As such, it is clearly the legislative intent not to limit the patents in Article 76 to those registered in PIRPAD. Accordingly, the courts should not make such a limitation either.

IPO suggests that Article 2 be revised to clarify that the term "drug" include both chemical and biological products, and define a "patents right relevant to drug application" as a patent that relates to an approved product (chemical or biological) that claims the approved product's active ingredient, pharmaceutical composition or formulation, method of manufacturing of the active ingredient, or approved medical use.

We also suggest that Article 4 be deleted, and Article 18 be revised to apply to the cases involving patents that are registered in PIRPAD.

Article 3

As explained above in General Comments, the courts should allow relevant parties reasonable time to prepare for litigation, especially in the absence of notification. Article 3 of the Draft Provisions requires preliminary evidence regarding whether the technical solution of drug applied for registration falls within the protection scope of the relevant patent right to be submitted at the time of filing a lawsuit. IPO suggests adding language to Article 3 to clarify that the court should take into consideration when the relevant party received notification about the generic drug application filing in evaluating the sufficiency of the preliminary evidence.

Article 7

For clarification purposes, we suggest deleting "generally" in the last phrase "the people's court generally shall not support."

Article 8

The second part of Article 8 of the Draft Provisions provides that the people's court may confirm, at the request of the applicant for drug marketing authorization, that the technical solution relevant to the drug for which registration is sought does not fall within the protective scope of the relevant patent right, when the patent is found to be invalid by the State Council's patent administration department or the first-instance administrative judgement. It is unclear on what basis the court would determine whether the technical solution falls within the protective scope of the patent right. IPO suggests deleting this part of Article 3 or clarifying the legal basis.

Article 9

The first paragraph of Article 9 of the Draft Provisions provides, among other things, that the people's court may confirm, at the request of the applicant for drug marketing authorization, that the technical solution relevant to the drug applied for registration does not fall within the protective scope of the relevant patent right, when an applicant asserts that there exists a statutory circumstance that it is not considered as patent infringement. We believe that the statutory circumstances that are not considered as patent infringement should fall under the circumstances stipulated in Article 75 of the Patent Law. As this Draft Provision deals with situations involving the initiation of litigation in Article 76 of the Patent Law, it is neither necessary nor appropriate to further interpret Article 75. Therefore, we suggest deleting "or asserts that there exists a statutory circumstance that it is not considered as patent infringement" in the first paragraph.

The second paragraph of Article 9 deals with the situation where the generic drug applicant asserts that the relevant patent right obviously falls under the circumstance that it should be declared invalid. Although this paragraph does not authorize the court to make a judgment on validity of the patent, it suggests that the court can review the validity of the patent based on the defense of the generic drug applicant. This could subject the patent to two parallel track invalidity proceedings, putting the patentee at an unfair disadvantage. Therefore, we suggest deleting this paragraph.

Article 12

IPO welcomes Article 12 of the Draft Provisions, as it recognizes the possibility that partial infringement may affect the outcome of the generic drug application. To further clarify the purpose of making separate determinations, we suggest adding "to help the State Council's drug regulation department make approval decisions accordingly."

Article 13

Article 13 of the Draft Provisions is directed to the situation in which the relevant technical solution of the drug application submitted by the applicant to the court is obviously inconsistent with the technical materials submitted to the drug regulation department. It refers to Article 111 of the Civil Procedure Law, which stipulates penalties such as fines and detention or even criminal liabilities to parties with acts such as forging or destroying important evidence. However, Article 111 does not address how obvious inconsistency would affect the patent litigation itself. IPO suggests revising Article 13 to include language similar to that of Article 25 of the SPC's Provisions on Evidence in IP Civil Litigation, which provides that the court may presume that the opposing party's claims about the matters involving the evidence are established when a party submits false evidence without justifiable reasons.

Article 15

Article 15 of the Draft Provisions provides that the patentee or an interested party can bring a separate patent infringement suit if an effective judgement holding that the relevant technical solutions of the drug applied for registration fall within the protective scope of the relevant patent right is made after the market approval. IPO points out that, in this situation, the patent linkage system would be meaningless without providing injunctive relief to the patentee and interested party. As such, we suggest adding the following paragraph to Article 15:

> Where a patentee or an interested party applies for injunctive relief in the patent infringement action as mentioned in the first paragraph of this Article, and using as evidence the aforementioned effective judgment holding that the relevant technical solutions of the drug applied for registration fall within the protective scope of the relevant patent right, requesting that the applicant for drug marketing authorization be prohibited from committing or about to commit an act of manufacturing, using, offering to sell, selling or importing for the purposes of production and business within the valid term of the relevant patent right, the people's court shall support the application.

Article 17

Article 17 of the Draft Provisions appears to be related to the good faith requirement in Article 20 of the Patent Law, which prohibits abuse of patent rights to harm the public interests or the legitimate rights and interests of others. IPO had previously submitted comments during various stages of drafting of the Patent Law to request clarification and guidance as to what constitutes "abuse of patent rights." Similarly here, IPO respectfully asks the SPC for a definition of "abuse of patent rights" through linkage to clear legal concepts. We are greatly concerned that, without such a definition, Article 17 may impose excessive liability on a patentee or interested parties that exercise the right of litigation and then potentially face unforeseeable risks.

At the very least, IPO suggests it be clarified that all claims having not been supported cannot by itself be the basis of a legal action for compensation for the damage or litigation fees. For example, a party could lose a litigation due to limitation in time and access to the information needed. A negative outcome in a litigation does not alone indicate a misuse of patent right.

Therefore, we suggest deleting "or all claims have not been supported" from Article 17. We also suggesting deleting Article 17 entirely unless a clear definition is provided for "abuse of patent rights."

IPO thanks the Supreme People's Court 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