二零二零年八月十三日

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全国人民代表大会常务委员会法制工作委员会
沈春耀主任

**邮寄**

**主题：《中华人民共和国专利法修正案(草案二次审议稿)》的反馈意见**

尊敬的沈主任您好：

美国知识产权所有人协会(下称“IPO 协会”)感谢有机会对 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)》(下称“《草案》”)提交意见的机会。

IPO协会是一家代表各行业、各技术领域内拥有知识产权或相关权益的公司和个人的国际性行业协会。它拥有一百七十五家公司会员以及大约一万两千名个人会员。这些个人会员有些从属于公司会员或律所成员，有些是发明人、作者或律师会员。IPO 协会的会员遍及三十多个国家。

IPO协会提倡有效和实惠的知识产权，为会员提供广泛的服务，包括支持会员在立法和国际事务中的利益、分析当前知识产权问题、提供教育和信息服务、以及向公众传播知识产权的重要性。

IPO 协会感谢《草案》似乎反映了近期中华人民共和国与美利坚合众国第一阶段经济和贸易协议（下称“第一阶段协议）中的某些规定。第一阶段协议体现了加强两国在专利保护方面的合作，事实上，IPO 协会认为此次公开征求意见是该两国间协议的重要且有益的落实。我们欢迎对于现实关切给与的关注，这些关切涉及专利权行使，还涉及专利权侵权有效救济的进展。专利法通过保护对于创新的投入而鼓励各主体进行创新。用于解决专利权相关争议的、公平且富有效率的机制是任何一个有效专利制度的重要部分。

我们高兴地看到，该《草案》将局部外观设计包括在内，扩大了外观设计专利的保护，并将其专利期限延长至 15 年。这些变化为申请人在工业设计方面的工作和投入提供了更大的认可，并进一步使中国的法律与其他主要司法辖区（例如，美国、欧盟、日本和韩国）的法律协调一致。

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在下述反馈意见中，IPO 协会强调了在《草案》中对于专利期限延长和专利链接方面提供更清晰和更详细规定的重要性。我们希望提请注意的是，对于制药公司在药物临床开发阶段所做的巨大投入，专利法上的认可是重要的，由于专利期限的原因，这种认可可能会在药品审评审批期间受到损失。

此外，目前中国没有数据保护制度。在没有数据保护制度的情况下，或者在专利法中没有规定从新药上市批准之日起至少四年内不得提交后续申请的情况下，IPO 协会关切的认为目前的《草案》可能不足以保护创新主体，该类创新主体在这些数据的产生过程中耗费了大量资源并在药物研发和审批过程中承担风险。

《草案》涉及了职务发明的权利以及发明人报酬问题。IPO 协会认为，加强发明人的权益以及回报单位对创新的投入对于专利制度是重要的。对此，IPO 协会谨建议，《草案》明确规定单位和员工可以自行达成协议来确定适当的发明人报酬，并明确允许单位和员工商定的任何形式的报酬（例如，一次付清或现金性奖金）。

关于法定损害赔偿和故意侵犯专利权的赔偿，我们强调补偿性损害赔偿的目的是充分补偿专利权人的经济损失。其关键在于，专利法应提供手段以引导法院确定适当的数额，以使专利权人得到完全补偿。此外，由于故意侵犯专利权的赔偿是以补偿性赔偿的金额为基础的，因此关键在于，所判给的补偿性赔偿的金额应能完全补偿专利权人的损失，而这对于防止将来的侵权行为犹为关键。

《草案》在一定程度上使行政机关承担了更大的职责，以进行调查、裁定责任、没收违法所得、处以损害赔偿和罚款、禁止进一步活动以及没收或销毁与专利侵权有关的产品。我们理解，如所提议的，所增加的职责可能会提升解决此类侵权问题的速度和效率，从而使诉讼当事人受益。但是，我们谨此提出，在促进利用行政管理机构解决专利纠纷和信任行政管理机构解决专利纠纷方面，与人民法院相比，这种促进和信任需要为诉讼当事人提供与经由司法审查相同程度的一致性、可预期性、透明度和程序保障。

我们希望我们的反馈意见能对《草案》定稿过程有所帮助，并为中国专利法的未来发展提供参考。

**第二条**

IPO 协会欢迎对第二条的修改，该修改将为局部外观设计提供保护。这一修改将增强与其它主要司法辖区（例如，美国、欧盟、日本和韩国）的协调性。另外，通过将图形用户界面（下称“GUI”）设计与其显示设备的外观分离来对 GUI 进行保护保护，将增强 GUI 设计创新的驱动力。在现代社会中，这一点越来越重要，许多 GUI 设计是独立开发的，并会在多种设备中使用。这一改变还将使工业设计各个领域的申请人能够将保护重点放在其设计的显著方面，从而更好地保护其创新的视觉印象。

第六条

第六条规定了单位与员工之间与发明权属有关的权利，以及对于产生自职务发明创造的专利权的申请或处置的权利。我们建议，无论是否存在雇佣关系，以及无论是否使用单位的材料，当事人均可以行使合同自由来针对发明创造确定权利，并且在订有合同的情况下，合同优先。在没有此类合同的情况下，则适用第六条的第一款和第二款，如下所示：

> 执行本单位的任务或者主要是利用本单位的物质技术条件所完成的发明创造为职务发明创造。职务发明创造申请专利的权利属于该单位；申请被批准后，该单位为专利权人。该单位可以依法处置其职务发明创造申请专利的权利和专利权，促进相关发明创造的实施和运用。
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> 非职务发明创造，申请专利的权利属于发明人或者设计人；申请被批准后，该发明人或者设计人为专利权人。
>
> **利用本单位的物质技术条件所完成的对于**发明创造**，无论发明人或者设计人是否被单位聘用**，单位与发明人或者设计人订有合同，对申请专利的权利和专利权的归属作出约定的，从其约定。

第十五条（原第十六条）

根据第十五条第一款，一旦单位被授予专利权，则该单位应当对职务发明创造的发明人或者设计人给予奖励，并且一旦被授予专利权的发明实施后，该单位应当根据应用的范围和取得的经济效益支付合理的报酬。

我们建议，通过遵守单位的职务发明创造奖励和报酬政策，或通过遵守单位与发明人（或者设计人）之间的协议,应认为单位履行了第十五条对发明人的义务。

更具体地说，IPO 协会同意加强发明人权益对专利制度是重要的。但是，我们对《草案》中对单位-员工合同处理方面可能存在的含糊之处表示关注。我们认为，《草案》需要进行修改，以明确表明单位和员工可以自行达成协议来确定职务发明创造的适当的发明人报酬或其它奖励，并且明确允许单位和员工就任何形式的报酬达成协议。

发明的市场价值通常要等到提交专利申请后多年后才知道，并且基于行业间的众多差异，员工和单位可以自由制定协议来确定员工的报酬，这对双方是有益的。例如，许多员工更喜欢更高的固定工资和针对职务发明创造的标准化奖励，而不是

与新技术不可预测的商业成功挂钩的基于业绩的可变报酬。同样，单位（尤其是在高科技、制药和其它行业中，这些行业每年在研发上投入数十亿美元）能够公平地收回其巨额投资，同时还可以根据各方商定的职务发明创造的附加值适当地奖励员工贡献者。

我们还注意到，根据目前的《草案》，单位为发明人或者设计人提供报酬的义务延伸到了专利权被授予受让人而不是该单位的情况。这样的条件似乎不合理，也给雇主单位带来了潜在的重大管理负担。也就是说，我们认为在发明转让后要求发明人或者设计人的所在单位支付奖励和报酬是不合理的。通常情况下，雇主单位可能不会从受让人的实施中获得任何经济利益。单位不得不跟踪受让人对专利的实施情况，这也是不公平且持续的管理负担。

因此，我们建议对第十五条第一款进行如下修改：

> 被授予专利权的单位应当对职务发明创造的发明人或者设计人给予奖励；发明创造专利实施后，根据其推广应用的范围和**取得的单位获得的**经济效益，对发明人或者设计人给予合理的报酬。**遵守单位的职务发明创造奖励和报酬政策，或者遵守单位与发明人或者设计人之间的职务发明创造奖励和报酬协议，应当被认为履行了对发明人或者设计人给予奖励并在实施后给予合理的报酬的义务。**

根据第十五条第二款，国家鼓励被授予专利权的单位实行产权激励，采取股权、期权、分红等方式，使发明人或者设计人合理分享创新收益。

鉴于上述对第一款的修改，我们建议删除第十五条第二款，以避免限制单位满足第十五条规定的激励义务的方式。

作为另外一种方式，在单位的职务发明创造奖励和报酬政策或协议并未涵盖的情况下，我们建议明确这些是可选的而非强制性的机制，并进一步建议对第十五条第二款进行以下修改：

> **尽管不是强制性的，但**国家鼓励被授予专利权的单位实行**产权**激励，采取股权、期权、分红**、现金性奖金**等方式~~**，使发明人或者设计人合理分享创新收益。**~~

第二十条

对于专利权的取得和行使，第二十条提到了诚实信用原则。该条款进一步规定，不得滥用专利权损害公共利益或者他人合法权益。第二十条还规定，滥用专利

权，排除或者限制竞争，构成垄断行为的，依照《中华人民共和国反垄断法》（下称“《反垄断法》”）处理。

关于诚实信用的要求，我们注意到这一概念在《中华人民共和国民法总则》第七条中规定为“民事主体从事民事活动，应当遵循诚信原则，…”。但是，“诚实信用”一词并未明确定义。同样，对于哪些将构成第二十条下的“公共利益”、“损害公共利益”和“滥用专利权”，我们也希望得到进一步的指导。在这方面，我们谨敦促通过与明确的法律概念的关联来澄清这些用语。否则，这些用语过于含糊，无法构成足够明确、具体或可管理的标准来指导法院或行政机关，可能会造成很大的不确定性，阻碍专利的合法使用。如不作进一步澄清，该规定可能与《与贸易有关的知识产权协议》（下称“TRIPS 协议”）第三十条产生潜在的冲突，该条款规定，“成员方可对专利授予的独占权规定有限的例外，条件是该例外规定没有无理地与专利的正常利用相冲突，也未损害专利所有者的合法利益，同时考虑到第三者的合法利益”。

本条第二款确认了《反垄断法》在“滥用专利权，排除或者限制竞争，构成垄断行为的”情形下的适用。由于第二款中《反垄断法》的引入，我们认为第一款中的“不得滥用专利权损害公共利益或者他人合法权益”的额外表述已经没有必要了，并且可能会造成进一步的混淆，因此我们建议将其删除。因此，IPO 协会建议进行以下修改：

> 申请专利**和行使专利权**应当遵循诚实信用原则。**不得滥用专利权损害公共利益或者他人合法权益。**~~—~~
>
> **滥用专利权，排除或者限制竞争，构成垄断行为的，依照《中华人民共和国反垄断法》处理。**

同时，IPO 协会谨提出，专利是政府授予的排他性权利，用于交换发明对公众的公开。这种排他性权利是对创新的重要激励，也是专利体系的基石。合理地利用专利权排除和限制竞争并不构成《反垄断法》下的“滥用专利权”。

此外，为了使专利权人更好地理解其专利权的范围，此处审慎的敦促根据《反垄断法》第五十五条就专利权人的安全港提供进一步的指导，以便在行政机关或人民法院对安全港进行审查时，能够更加一致、可预期且透明地适用《反垄断法》第五十五条。

## 第二十一条

IPO 感谢法制工作委员会为加强国务院专利行政部门（下称“专利行政部门”）运作的透明度所做的努力。但是，我们认为，作为可以并应该进一步做出的努力，应该在《专利法》中明确要求公布专利行政部门的决定（例如，关于专利有

效性的决定）。公布决定将促进法律的统一适用，建立专业人员和公众对专利行政部门的信心，并通过使专业人员了解专利行政部门做出决定的方式，促进更有效的宣传。因此，IPO 协会建议对第二十一条第二款进行如下修改：

> 国务院专利行政部门应当加强专利信息公共服务体系建设，完整、准确、及时发布专利信息，提供专利基础数据，定期**公布其决定和**出版专利公报，促进专利信息传播与利用。

第二十二条

除了其它问题，第二十二条涉及了“现有技术”的构成。虽然对该条款没有修改提案，但我们建议澄清其语言，使得“国内或国外”为公众所知的技术将构成的现有技术，以确定可专利性。

> 本法所称现有技术，是指申请日以前在国内**或国**外为公众所知的技术。

第四十二条

对于第四十二条第一款中的外观设计专利保护，IPO 赞扬对第四十二条的修改，该修改将外观设计专利的期限延长至自申请之日起十五年。这一修改为申请人在工业设计方面的工作和投入给予了更大的认可，并使该期限与其他主要司法辖区（例如，美国、欧盟、日本和韩国）提供的保护期限更加协调一致。

关于第四十二条第二款中规定的专利期限调整（下称“PTA”），我们认为《草案》应明确 CNIPA 或其它指定部门将受理和管理 PTA 请求。此外，我们希望得到针对 PTA 计算方法的更详细的指南，尤其是希望对“不合理延迟”的认定给予澄清。

关于第四十二条第三款中规定的专利期限延长（下称“PTE”），IPO 建议《草案》应明确国家药品监督管理局（下称“NMPA”）负责协助 CNIPA 确定专利期限延长。具体来说，NMPA 应该被赋予确定药品审批所占用时间的职责，包括临床试验和审评的时长，以及上市申请审批的时长。

《草案》似乎规定由国务院专利行政部门（即，CNIPA）自由裁量决定是否给与 PTE。IPO 协会建议《草案》应阐明，将依请求并根据具体且透明的 PTE 计算公式来批准每项 PTE 请求，以符合第一阶段协议的要求，

《草案》规定，国务院可以延长“新药发明专利”期限。根据中国在第一阶段协议中的承诺，我们将“发明专利”解释为包括覆盖药物、批准的药物使用方法或药物制造方法的专利，而“新药”则包括所有具有完整安全性和有效性数据支持且尚未在中国获得批准的小分子药物和和生物制品，而无论其在国外的批准状况如何。因此，我们敦促《草案》明确确认 PTE 可用的专利和产品的范围。

为此，我们建议以下内容：

> 为补偿新药**临床开发和**上市审评审批占用时间，对~~在中国获得上市许可的~~**覆盖在中国批准上市的新药产品、其被批准的使用方法或该产品的制造方法的新药**发明专利，国务院专利行政部门~~可以~~**应当**应专利权人的请求给予期限补偿。补偿期限不超过五年，新药上市后总有效专利权期限不超过十四年。

另外，我们请求澄清专利期限延长的范围，即，是否可获得专利期限延长是基于首次批准上市的特定产品、活性成分还是活性部分来判断。希望更具体的说明已知活性成分的新盐、含有已知活性成分的新制剂或组合物，或已知活性成分的新适应症是否可获得 PTE。

此外，对于那些已经上市并且在本专利法修正案颁布之时该发明专利符合 PTE 规定的那些新药，我们建议增加过渡期，以使专利权人可以在专利法颁布后的一定时间内（例如，三个月）提交 PTE 申请。

## 第四十八条

第六章（“专利实施的特别许可”）第四十八条规定，“国务院专利行政部门、地方人民政府管理专利工作的部门应当会同同级相关部门采取措施，加强专利公共服务，促进专利实施和运用”。在此谨审慎的敦促对于第六章给予特别的注意，以限制通过设定强制许可而采取此类措施的情况，从而不至减少对投入时间和精力来促进科学技术进步、造福社会的发明人、设计人的激励。

## 第五十八条

在阅读第五十八条时，我们注意到提到了第四十八条第二款。第五十八条还涉及根据第四十八条第二款或第五十条的规定授予的强制许可。经修改后，已经没有第四十八条第二款。同时，第五十条涉及开放许可而不是强制许可。我们建议对第五十八条进行适当的修改以纠正上述情况。

## 第五十九条

第五十九条涉及根据第四十八条第一款或第五十一条申请强制许可。第四十八条中只有一个条款。而且，第五十一条涉及开放许可而不是强制许可。我们建议对第五十九条进行适当的修改以纠正上述情况。

第六十六条

本条第一款涉及新产品制造方法专利的举证责任倒置，在这种情况下，被告应提供证明其方法不同于专利方法的证据。我们建议做出澄清，被告的此类证明应是提供给人民法院或管理专利工作的行政机关。此外，在被告的证据包含商业秘密的情况下，法院或者行政机关应采取适当的保密措施，以防止公开披露。因此，我们建议对第一款进行以下修改：

> 专利侵权纠纷涉及新产品制造方法的发明专利的，制造同样产品的单位或个人应当**向人民法院或者管理专利工作的部门**提供其产品制造方法不同于专利方法的证明。**在被告的证据包含商业秘密的情况下，人民法院或者管理专利工作的部门应当提供适当的保密措施，以防止信息公开披露**。

第六十六条第二款涉及实用新型专利和外观设计专利，这些专利的授权无需实质审查。与发明专利相比，实用新型专利和外观设计专利的有效性存在更大的不确定性。对此，不存在（如发明专利所具备的）有效性推定，实用新型专利或外观设计专利的专利权人应基于专利行政部门提供的专利权评价报告进行初步证明。因此，谨建议人民法院或者行政机关应当要求以实用新型专利或外观设计专利为基础主张专利权的当事人出具专利行政部门的专利权评价报告。因此，IPO 协会建议对第二款进行以下修改：

> 专利侵权纠纷涉及实用新型专利或者外观设计专利的，人民法院或者管理专利工作的部门**可以应当**要求**专利权人或者利害关系人主张该专利权的当事人**出具由国务院专利行政部门对相关实用新型或者外观设计进行检索、分析和评价后作出的专利权评价报告，作为审理、处理专利侵权纠纷的证据；~~**专利权人、**~~**被控侵权人或者其它**利害关系人~~**或者被控侵权人**~~也可以主动出具专利权评价报告。

第六十九条

《草案》第六十九条扩大了专利管理和执法部门的调查权限，除假冒专利案件以外使其包括了专利侵权案件。与调查通常仅涉及核实专利权属的假冒专利案件不同，专利侵权案件通常涉及保密的技术和商业信息。我们关切的认为，赋予专利管理和执法部门广泛的权力来检查涉嫌侵权行为发生的场所以及查阅和复制相关文件而不提供适当的保障措施来保护此类保密信息，这可能会给保密信息带来重大的被披露风险。IPO 协会谨建议在第六十九条中增加以下内容：

**管理专利工作的部门和负责专利执法的部门所进行的调查应当确保技术和商业信息的保密性得以维持。**

第七十条

第七十条涉及国务院专利行政部门和地方人民政府管理专利工作的部门对于专利侵权纠纷的处理。

第七十条第一款规定专利行政部门可以处理“在全国有重大影响”的专利侵权纠纷。我们恳请进一步解释“在全国有重大影响”。

我们也谨此提出，由这些部门作出的任何决定的执行均应等待包括司法程序在内的上诉程序的结果。我们认为，为确保行政执法受到司法审查，修改是必要的。因此，建议在第七十条增加以下内容：

**国务院专利行政部门和地方人民政府管理专利工作的部门应当中止执行或者以其它方式不执行任何决定，直至当事人穷尽包括司法程序在内的上诉程序。**

第七十一条

《草案》第七十一条规定了法定损害赔偿的最高限额为五百万元人民币，以及确定用于计算故意侵犯专利权赔偿数额的倍数（最高五倍），并说明了如何确定补偿性赔偿数额。

补偿性赔偿作为惩罚性赔偿的依据

我们对第七十一条（原第六十五条）没有规定足够的补偿性赔偿表示关注。尽管当前《草案》将法定损害赔偿提高到了五百万元人民币，但在很多情况下，这一数额仍然显著不足以补偿专利权人。

补偿性赔偿旨在对专利权人因侵权行为而遭受的经济损失和其它损失提供充分补偿。如果补偿性赔偿不足以完全补偿专利权人，专利将无法为创新以及承担风险而创业或扩大已有业务提供适当的激励。作为后果，专利制度将不太可能刺激有益于社会的商业活动的增长。

故意侵犯专利权的赔偿（即，惩罚性赔偿）是根据判给的补偿性赔偿而确定的。如果补偿性赔偿不足，由人民法院自由裁量的惩罚性赔偿数额也可能无法起到对故意侵犯专利权进行惩罚的目的。因此，至关重要的是，尤其是为了阻止将来的

侵权行为，补偿性赔偿（即，不考虑惩罚性赔偿）应充分补偿原告因侵权而遭受的损害。

故意侵犯专利权的赔偿（惩罚性损害赔偿）

修改后的第七十一条规定了，对故意侵犯专利权，情节严重的，赔偿数额可以是补偿性赔偿的一倍以上五倍以下。

如上所述，专利权人需要获得能够完全补偿其因侵权行为而造成的损失的补偿性赔偿。在具有完全补偿性救济的情况下，IPO 协会的立场是，旨在惩罚侵权人故意侵犯专利权的惩罚性赔偿不应超过补偿性赔偿的三倍，这与许多其它主要司法辖区的标准一致。因此，我们建议进行以下修改：

> **对故意侵犯专利权，情节严重的，可以在按照上述方法确定数额的一倍以上~~五~~三倍以下确定赔偿数额。**

故意侵犯专利权的认定

第七十一条未定义“故意侵犯专利权”一词。关于“情节严重”的认定，我们注意到，最高人民法院发布了《最高人民法院关于加大知识产权侵权行为制裁力度的意见（征求意见稿）》（下称“《意见》”，于 2020 年 6 月 15 日发布并公开征求意见），该《意见》在第十五条中定义了侵权“情节严重”的因素。我们期待在最终的《意见》中得到进一步的指导。

我们认为，至少在被告恶意侵犯专利权的情况下，将会构成“故意侵犯专利权，情节严重”，并根据第七十一条的规定获得损害赔偿的增加。根据我们的经验，对于“故意侵犯专利权”更详尽的指导将有助于法院和行政机关判定侵权行为是否属于“故意”。为此，请参考 IPO 协会于 2019 年 2 月 2 日关于前一次专利法修正案的信函，我们建议在专利法第七十一条或后续的法规或解释中列举以下因素供法院在确定故意侵犯专利权时考虑：

（一）侵权人的侵权行为是否有恶意；
（二）侵权人的行为是否与业界行为标准一致；
（三）侵权人是否故意复制权利人有专利覆盖的产品；
（四）侵权人是否合理地相信自己未侵权；
（五）侵权人是否合理地相信相关专利无效；
（六）侵权人是否为避免侵权做过真诚的努力，例如对专利做过规避设计；
（七）侵权人是否试图掩盖侵权行为；和
（八）侵权人是否合理地依赖于关于其行为不属于专利侵权或者专利无效或不能执行的法律意见书。

与侵权行为相关的账簿、资料

由于充分的补偿性救济的重要性，因此必须采取措施确保侵权人提供“与侵权行为相关的账簿、资料”，并就法院在判定补偿性赔偿时可以考虑的证据类型提供指导。

为此我们建议，将第七十一条中两个自由裁量的表述“可以”修改为强制性的“应当”。具体来说，我们建议对当前条款进行如下修改：

人民法院…，**可以应当**责令侵权人提供与侵权行为相关的账簿、资料；

…，人民法院**可以应当**参考权利人的主张和提供的证据判定赔偿数额。

以上两个修改建议反映这样一个事实，即，为了确定如何为侵权行为而补偿专利权人，通常需要确定侵权人的利润和销售额。这样的调查不应是自由裁量的，而且，将这种调查变为强制性的将确保各法院间适用的一致性。

此外，我们建议，无论是在《专利法》第七十一条中，或是在随后的法规或解释中，都应举例说明被告必须提供的、属于“与侵权行为相关的账簿、资料”的证据类型。具体而言，可以列举一系列示例，例如：销售量、利润表、零售额、销售利润以及其他此类证据。

对于第七十一条所规定的“侵权人不提供或者提供虚假的账簿、资料”的情况，我们还建议列举其它证据的示例（例如，专利权人提交的证据），法院可据此判定赔偿数额。此类示例可包括以下信息，例如：

- 侵权人关于销售或商业活动的公开声明，
- 侵权人在商店或其他渠道中的产品定价，
- 市场调查，
- 向政府机构提交的监管文件中的声明，
- 通过首次公开募股（IPO）公开的信息，
- 客户的收据，
- 第三方的零售销售信息，以及
- 其它有关侵权活动规模和范围的信息。

## 第七十五条

经修改的第七十五条包括了另外的与专利链接有关的规定。作为初步建议，IPO 协会认为专利链接应该是一项单独且独立的条款，而不是被列在针对专利侵权豁免的第七十五条下。

与第四十二条类似，我们建议对拟议的专利链接条款进行澄清，使其适用于小分子产品和生物药产品二者，并增加对于可纳入中国上市药品专利信息登记平台的药品专利种类的进一步说明。

我们还建议，应要求提交仿制药申请（ANDAs）的申请人通知专利权人、被许可人或参比产品的上市许可持有人，并且/或者要求其提供与侵权有关的证明或声明；并且，应规定允许专利权人（或其他利益相关方）自收到通知之日起至少 45 天内（而不是在 NMPA 公示仿制药申请人提交上市许可申请后的 30 天内）提起诉讼和/或行政裁决。

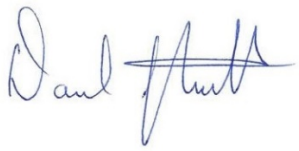
此外，本条款还应明确阐明，在司法或行政裁决程序中的前 24 个月内，NMPA 不批准处于专利纠纷解决过程中的待决上市申请。按照《草案》的规定，尚不清楚在专利诉讼或行政裁决未决期间，是否将自动中止仿制药的监管审查和审批程序。此外，《草案》未提及如果专利争议案件待决超过 9 个月，NMPA 是否具有给予仿制药申请人上市许可的自由裁量权。

如前所述，目前中国没有数据保护制度。在法律中没有数据保护制度规定从新药上市批准之日起至少四年内不得提交后续申请的情况下，IPO 协会关切的认为目前的《草案》可能不足以保护创新主体，该类创新主体在这些数据的产生过程中耗费了大量资源并在药物研发和审批过程中承担风险。

我们再次感谢法制工作委员会对 IPO 协会反馈意见的关注，我们也非常愿意进一步交流并能有机会提供更多的信息。

随信附上本信的翻译版本。

此致



Daniel J. Staudt
美国知识产权所有人协会主席

附件: 《中华人民共和国专利法修正案（草案二次审议稿）》的反馈意见（英文版）

13 August 2020

Mr. Shen Chunyao
Chairman, Legislative Affairs Commission, Standing Committee of the National People's Congress of the People's Republic of China
No. 1, Qianmen Street W
Xicheng District
Beijing 100805
People's Republic of China

***Via Courier***

***Re: The Patent Law of the People's Republic of China (Draft Revision) (July 3, 2020)***

Dear Chairman Shen:

The Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the request for comments on *The Patent Law of the People's Republic of China (Draft Revision)* ("Draft Revision") published on 3 July 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 that the Draft Revision appears to reflect 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"). Indeed, IPO views this invitation for comments as an important and useful implementation of the two countries' agreement to strengthen their cooperation regarding patent protection, as memorialized in the Phase One Agreement. We welcome the attention given to practical concerns regarding enforcement of patent rights and development of effective remedies for infringement of those rights. By protecting investments in innovation, patent law encourages parties to innovate. Fair and

efficient mechanisms for resolving disputes relating to patent rights are important parts of any effective patent regime.

We are pleased to see in this draft expanded protection for design patents to include partial designs and extend the patent term to fifteen years. These changes provide greater recognition for applicants' work and investment in industrial designs, and further harmonize China's laws with other major jurisdictions, such as the United States, European Union, Japan, and South Korea.

In our below comments, IPO emphasizes the importance of providing greater clarity and more detailed provisions regarding patent term extension and patent linkage in the Draft Revision. We wish to draw attention to the importance of the patent law's recognition of the significant investments made by pharmaceutical companies during the clinical development phase of a drug which, as a result of the patent term, can be lost during regulatory review.

Moreover, currently there is no regulatory data protection in China. Without regulatory data protection or provisions in the patent law specifying that no follow-on applications shall be filed within a period of at least 4 years from marketing approval of the new drug, IPO is concerned that the Draft Revision as it stands may be inadequate to protect innovators who expend significant resources in developing such data and undertake risks in the path towards drug development and approval.

The Draft Revision addresses rights to service inventions and inventor remuneration. IPO believes that strengthening inventor rights and interests, and rewarding an employer's investment in innovation, are important to the patent system. In that regard, IPO recommends that the Draft Provision make clear that employers and employees can reach their own agreements defining appropriate inventor compensation, and expressly allow for any form of compensation (such as a lump sum or cash bonus), that an employee and employer agree on.

In regard to statutory damages and compensation for willful infringement, we emphasize that the objective of compensatory damages is to fully compensate the patent owner for their financial losses. It is critical that patent laws provide the means to guide the courts in determining an appropriate amount to make the patent owner whole. Moreover, because compensation for willful infringement is based on the amount of compensatory damages, it is critical, especially for purposes of discouraging future infringement, that the amount of compensatory damages awarded fully compensate the patentee's loss.

The Draft Revision provides, in part, a greater role for the administrative authorities to investigate, adjudicate liability, confiscate illegal earnings, impose damages and fines, enjoin further activities and confiscate or destroy products associated with patent infringement. We appreciate that the increased responsibilities, as proposed, may enhance the speed and efficiency in the resolution of such infringement matters for the benefit of the litigants. However, we respectfully note that in promoting use of and confidence in the administrative agencies for patent dispute resolution, as compared with the people's court, such promotion and confidence requires the same degree of uniformity, predictability, transparency, oversight, and procedural protections that are provided to the litigants through judicial review.

We hope that our detailed comments below will be helpful during the process of finalizing the Draft Revision, as well as inform future developments in Chinese patent law.

**Article 2**

IPO welcomes the amendment to Article 2 that would enable protection for partial designs. This change will increase harmonization with other major jurisdictions, such as the United States, European Union, Japan, and South Korea. It will enhance the incentive for innovation in graphical user interface (GUI) design by enabling protection for GUI designs separate from the appearance of their display devices. This is increasingly important in the modern world, where many GUI designs are developed independently and used across a wide variety of devices. This change will also allow applicants in all areas of industrial design to focus protection on significant aspects of their designs to better protect the visual impressions of their innovations.

**Article 6**

Article 6 addresses the rights between employers and employees regarding ownership of the invention and rights to apply for or dispose of the patent rights as a result of employment service inventions. We recommend that, whether or not an employment relationship exists, and whether or not an employer entity's materials are used, that the parties can exercise freedom to contract to determine the rights to an invention-creation, and where there is a contract, that contract will prevail. In the absence of such a contract, then the first and second paragraphs of Article 6 will apply, as shown below:

> *An invention made in carrying out tasks of an entity or made by taking advantage of the material and technical means of the entity is a service invention. The right of patent application of a service invention belongs to the entity. After the patent is granted, the entity is the patentee.*
>
> *For any non-service invention, the right of patent application belongs to the inventor or designer. After the application is approved, the inventor or designer shall be the patentee. The entity may dispose of the right of patent application and the patent right of a service invention in accordance with the law, and promote the implementation and application of the relevant invention.*
>
> *For an invention-creation ~~made by taking advantage of the material and technical means of an entity~~* ***whether or not the inventor or designer is employed by the entity****, the right of patent application and the ownership of the patent shall be determined by agreement between the entity and the inventor or designer, if any.*

**Article 15 (original Article 16)**

Under paragraph 1 of Article 15, once an employer entity has been granted a patent right, the employer entity is mandated to pay the inventor (or creator or designer) of a service invention-creation both a reward and, once the patented invention has been exploited, a

reasonable remuneration based on the scope of the application and the economic benefits yielded.

We recommend that the Article 15 obligations to the inventors be considered satisfied by compliance with the employer entity's service invention-creation reward and remuneration policy, or by compliance with an agreement between the employer entity and inventor (or creator or designer).

More particularly, IPO agrees that strengthening inventor rights and interests are important to patent systems. We are concerned, however, with potential ambiguity regarding treatment of employer-employee contracts in the proposed amendment. We believe that the Draft Provision requires modification to make clear that employers and employees can reach their own agreements defining an appropriate inventor compensation or other reward for service invention-creations, and to expressly allow for any form of compensation that an employee and employer agree on.

The market value of an invention is often unknown until years after a patent application is filed, and based on the many differences among industries, employees and employers benefit from being able to freely form their own agreements defining employee compensation. For example, many employees prefer higher guaranteed salaries and standardized rewards for service invention-creations, as opposed to variable performance-based compensation tied to the unpredictable commercial success of a new technology. Similarly, employers – particularly in high-tech, pharmaceutical, and other industries where billions in investment are spent annually in research and development – may be able to fairly recoup their large investments while also appropriately awarding employee contributors based on the incremental value of their service invention-creations as agreed to by the parties.

We also note that, as presently drafted, the employer entity's obligation to remunerate the inventor (or creator or designer) extends to situations where the patent rights are granted to an assignee other than the employer entity. Such conditions seem unreasonable, as well as create a potentially significant administrative burden for the employer entity. We believe it is unreasonable to mandate that the employer entity to which the inventor (or creator or designer) belongs pay a reward and remuneration after the invention has been assigned. Often the employer entity may not be receiving any economic benefits from the assignee's exploitation. It is also an unfair ongoing administrative burden placed on the employer entity to have to track the exploitation of the patent by the assignee.

Accordingly, we propose the following revisions to paragraph 1 of Article 15:

> *The entity that is granted a patent right shall award to the inventor, ~~or~~ creator* ***or designer*** *of a service invention-creation a reward and, upon exploitation of the patented invention-creation, shall pay the inventor, ~~or~~ creator* ***or designer*** *a reasonable remuneration based on the extent of spreading and application and the economic benefits* ***obtained by the entity*** *~~yielded~~.* ***The obligation to award inventors, creators or designers a reward and upon exploitation a reasonable remuneration shall be considered fulfilled by compliance with the entity's service invention-creation award and remuneration policy or with the service invention-creation awards***

***and remuneration agreement between the entity and inventor, creator or designer.***

Under paragraph 2 of Article 15, the State encourages the employer entity that is granted a patent right to implement property incentives, such as equity, option, and dividend, etc., to enable inventors or designers to reasonably share the profits brought by the invention-creation.

We recommend deleting paragraph 2 of Article 15 in view of the above-noted revisions to paragraph 1, and in order to avoid limiting the ways in which an employer entity may meet its incentive obligations under Article 15.

In the alternative, and to the extent not already covered under an employer entity's service invention-creation reward and remuneration policy or agreement, we propose to make clear that these are optional and not mandatory mechanisms, and further recommend the following revisions to paragraph 2 of Article 15:

> ***Although not mandatory, t****~~T~~he State encourages the entity that is granted a patent right to implement ~~property~~ incentives, such as equity, option, ~~and~~ dividend, **cash bonus**, etc. ~~to enable inventors or designers to reasonably share the profits brought by the invention-creation~~.*

**Article 20**

In securing and exercising one's patent rights, Article 20 speaks to the principle of good faith. This article further mandates that one shall not abuse these patent rights by harming the public interest or the legitimate rights and interests of others. Article 20 also states that abusing ones' patent rights to exclude or restrict competition, when constituting a monopoly, shall be treated in accordance with the Anti-Monopoly Law ("AML") of the People's Republic of China.

With respect to the requirement of good faith, this concept is stipulated in Article 7 of *General Provisions of the Civil Law of the People's Republic of China*, which states that "parties to civil legal relations shall conduct civil activities under the principle of good faith . . . ." However, the term "good faith" is not clearly defined. Similarly, we seek further guidance as to what constitutes "public interest," "public harm," and "abuse of patent rights" under Article 20. In this regard, it is respectfully urged that these terms be clarified through linkage to clear legal concepts. Otherwise, these terms are too vague to constitute sufficiently clear, specific, or administrable standards to guide courts or administrative agencies, which can create significant uncertainty and impede the legitimate use of patents. Without further clarification, this provision raises potential conflict with Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), which provides that the exceptions to the exclusive rights conferred by a patent should not unreasonably conflict with a normal exploitation of the patent and unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The second paragraph of this Article confirms the applicability of the Anti-Monopoly Law on the acts of "abusing patent rights to exclude or restrict competition, when

constituting a monopoly." With the inclusion of this second paragraph referencing the AML, we believe the additional statement "and shall not abuse patent rights to harm the public interests or the legitimate rights and interests of others" in the first paragraph is no longer necessary and may create further confusion, and thus we recommend deleting it. IPO therefore proposes the following revisions:

> *The application for patents* ~~***and the exercise of patent rights***~~ *shall follow the principle of good faith* ~~***and shall not abuse patent rights to harm the public interests or the legitimate rights and interests of others***~~*.*
>
> *Abusing patent rights to exclude or restrict competition, when constituting a monopoly, shall be treated in accordance with the Anti-monopoly Law of the People's Republic of China.*

At the same time, IPO respectfully submits that a patent is the government's grant of an exclusive right in exchange for the public disclosure of an invention. The right to exclude serves as an important incentive to promote innovation, and is the basis of the patent system. Therefore, proper use of patent rights to exclude and restrict competition does not constitute "abusing patent rights" under the AML.

Additionally, in order for a patent owner to better understand the metes and bounds of its patent rights, it is respectfully urged that further guidance be provided as to a patent owner's safe harbors under Article 55 of the AML so that a more uniform, predictable and transparent application of Article 55 of the AML can occur when such safe harbors are being reviewed by the administrative agencies or the people's courts.

**Article 21**

IPO applauds the Legislative Affairs Commission's efforts to enhance the transparency of the operation of the Patent Administration Department under the State Council ("Patent Administration Department"). However, we believe that effort can and should go further by expressly requiring in the Patent Law that decisions by the Patent Administration Department (*e.g.*, on patent validity) be published. Publication of decisions will promote the uniform application of law, build confidence in the Patent Administration Department by professionals and the public, and promote more effective advocacy by educating professionals on the ways in which the Patent Administration Department reaches its decisions. IPO therefore recommends that the second paragraph of this article be revised as shown below:

> *The Patent Administration Department Under the State Council shall strengthen the establishment of the public service system of patent information, regularly publish* ***its decisions and*** *patent gazettes and completely, accurately and timely announce the patent information to provide the basic data of patent information and promote the patent information spreading and utilization.*

**Article 22**

Article 22 addresses, among other issues, what constitutes "existing art" (or prior art). While this article is not being proposed for amendment, we recommend that the language be clarified so that art known to the public "domestically or abroad" would constitute existing art for purposes of determining patentability.

> *For the purposes of this Law, existing art means the art known to the public domestically* ***or*** ~~***and***~~ *abroad before the date of application.*

**Article 42**

With respect to design patent protection in the first paragraph of Article 42, IPO commends the amendment to Article 42 that extends the term of a design patent to fifteen years from the date of application. This change provides greater recognition for applicants' work and investments in industrial designs, and in will bring the term into closer alignment with the periods of protection offered in other major jurisdictions, such as the United States, European Union, Japan, and South Korea.

With respect to patent term adjustment ("PTA") provided in the second paragraph of Article 42, we believe that the Draft Revision should clarify that CNIPA or another designated department will receive and administer requests for PTA. In addition, we seek more detailed guidance on the calculation method for PTA, and particularly would like clarification on the determination of "unreasonable delays."

With respect to patent term extension ("PTE") provided in the third paragraph of Article 42, IPO recommends that the Draft Revision should clarify that the National Medical Products Administration ("NMPA") is responsible for assisting CNIPA in determining patent term extensions. Specifically, NMPA should be tasked with determining the time used for drug approval, including both the length of clinical trials and evaluation, and the length of the marketing application review.

The Draft Revision appears to leave it to the discretion of the Patent Administrative Department of the State Council (*i.e.*, CNIPA) whether to grant PTE. IPO recommends that Draft Revision should clarify that each PTE request will be granted upon request in accordance with a specific and transparent PTE calculation formula, consistent with the requirements of the Phase One Agreement.

The Draft Revision provides that "invention patents of new drugs" may be extended by the State Council. In accordance with China's commitments under the Phase One Agreement, we interpret "invention patents" to include patents that cover the drug, an approved method of using the drug, or a method of making the drug—and "new drug" to include all new small molecule drugs and biologics that are supported by full safety and efficacy data and have not yet been approved in China, regardless of its approval status abroad. Therefore, we urge that the Drat Provision explicitly confirm the scope of patents and products for which PTE is available.

To that end, we recommend the following:

> *The State Council ~~may~~ **shall** ~~make a decision to~~ extend the duration of invention patents ~~of innovative pharmaceuticals which have been approved for marketing in China,~~ **covering a new pharmaceutical product approved for marketing in China, its approved method of use, or a method of making the product** to make up the time used for drug **clinical development and** approval, and the extension period shall not exceed five years and the net effective duration of such ~~innovative pharmaceuticals~~ **new pharmaceutical product** which have market launches shall not exceed fourteen years*

We further request clarification to the scope of patent term extensions, *i.e.*, whether the extension will be available for the first marketing approval of a given product, an active ingredient, or an active moiety. More specificity regarding eligibility for PTE based on a new salt of a known active ingredient, a new formulation or composition containing a known active ingredient, or a new indication for a known active ingredient would be appreciated.

In addition, we recommend adding a transition period for those innovative drugs already on the market and for which the invention patent satisfies the PTE provisions at the time this Patent Law Amendment is enacted, so that the patentee may submit an application for PTE within a set period of time (*e.g.*, three months) of the enactment of the Patent Law.

**Article 48**

Article 48 within Chapter 6 ("Special License for the Exploitation of Patent") states that the "Patent Administration Department under the State Council and the Administrative Authority for Patent Affairs under the local people's government shall, together with the relevant departments at the same level, take measures to strengthen the public service for patent and promote the implementation and application of patent". It is respectfully urged that special care be taken under Chapter 6 to limit those instances where such measures are taken through the imposition of a compulsory license so as to not lessen the incentives accorded to inventors, creators, and designers who are investing time and effort toward the advancement of the sciences and technology for the benefit of society.

**Article 58**

In reviewing Article 58, we note that reference is made to a subparagraph 2 of Article 48. Article 58 also addresses the compulsory license granted in accordance with the provisions of Subparagraph 2 of Article 48 or Article 50. As amended, there is no subparagraph 2 of Article 48. Also, Article 50 is directed to an open license and not a compulsory license. We suggest appropriate amendments be made to Article 58 to correct the foregoing.

**Article 59**

Article 59 addresses an application for a compulsory license in accordance with subparagraph 1 of Article 48 or Article 51. There is only one paragraph within Article 48. Also, Article 51 is directed to an open license and not a compulsory license. We suggest that appropriate amendments be made to Article 59 to correct the foregoing.

**Article 66**

The first paragraph of this Article is directed to reversal of the burden of proof in cases relating to a patented process for making a new product, where the defendant shall produce evidence showing that its process is different from the patented process. We recommend clarification that such a showing by the defendant is to be provided to the people's court or the administrative authority adjudicating the patent matter. Moreover, where the defendant's evidence includes trade secrets, the court or the administrative entity should take appropriate confidentiality measures to protect against public disclosure. Thus, we recommend the following revision to the first paragraph:

> *Where any infringement dispute relates to a patent for invention for a process for the manufacture of a new product, any entity or individual manufacturing the identical product shall furnish proof* ***to the people's court or the administrative authority for patent affairs*** *to show that the process used in the manufacture of its or his product is different from the patented process.* ***Where the defendant's evidence includes trade secrets, the people's court or administrative authority for patent affairs should provide appropriate confidentiality measures to protect the information from public disclosure.***

The second paragraph of Article 66 addresses utility model patents and design patents, which are granted without substantive examination. Compared to invention patents, there is relatively more uncertainty about the validity of utility model patents and design patents. In this regard, there is not a presumption of validity (as afforded to invention patents), and the holder of a utility model or design patent should make a preliminary showing based on the patent evaluation report provided by the Patent Administration Department. Therefore, it is respectfully submitted that the people's court or the administrative authority shall require the party asserting the patent right based on a utility model patent or design patent to furnish an evaluation report made by the Patent Administration Department. IPO therefore proposes the following revision to the second paragraph:

> *Where the dispute of patent infringement relates to a patent for utility model or design, the people's court or the administrative authority for patent affairs* ~~***may ask***~~ ***shall require*** ~~***the patentee or interested part***~~ ***the party asserting the patent right*** *to furnish an evaluation report of the patent right made by the Patent Administration Department under the State Council after conducting search, analysis and evaluation of the relevant utility model or design as an evidence for trial and handling of the patent infringement disputes. The* ~~***patentee,***~~ ***accused infringer or other*** *interested party* ~~***or accused infringer***~~ *may also proactively submit the evaluation report of the patent right.*

**Article 69**

Article 69 of the Draft Revision expands the investigative authority of patent administration and enforcement departments to include patent infringement cases beyond patent passing-off cases. Unlike patent passing-off cases, where the investigation typically

only involves the verification of patent ownership, patent infringement cases often involve confidential technical and commercial information. We are concerned that giving patent administration and enforcement departments broad authority to inspect the sites where the alleged infringement act takes place and to review and copy relevant documents, without providing appropriate safeguards for the protection of such confidential information, might create a significant risk of disclosure of the confidential information. IPO respectfully recommends that the following be added to Article 69:

> *Investigations by the administrative authority for patent affairs and the administrative authority for patent enforcement should be conducted so as to ensure that the confidentiality of technical and commercial information is maintained.*

**Article 70**

Article 70 addresses the handling of patent infringement disputes by the Patent Administration Department under the State Council and the administrative department for patent affairs under the local people's government.

Under the first paragraph of Article 70, the Patent Administration Department may handle patent infringement disputes that are of "nationwide significance". We respectfully request further guidance as to how nationwide significance is to be construed.

It is also respectfully submitted that enforcement of any judgment imposed by these departments should await the outcome of the appeal process, including before the judiciary. We believe that an amendment is necessary to ensure that administrative enforcement is subject to judicial review. Accordingly, it is recommended that the following paragraph be added to Article 70:

> *The patent administration department under the State Council and the administrative department for patent affairs under the local people's government shall suspend and otherwise not enforce any judgment until and unless the appeal process, including before the judiciary, has been exhausted by the parties.*

**Article 71**

The amendments to Article 71 set a ceiling of RMB 5,000,000 for statutory damages, specify a multiplier (up to five times) to be used in computing compensation for willful infringement, and address how to determine the amount of compensatory damages.

Compensatory Damages as a Predicate for Punitive Damages

We express concern that Article 71 (Original Article 65) does not provide for adequate compensatory damages. Although the current amendments have raised the statutory damages to RMB 5,000,000, such a figure can still be substantially inadequate to compensate patent owners in many cases.

Compensatory damages are intended to provide full compensation to the patent right holder for their financial losses and other losses due to the act of infringement. If

compensatory damages are not adequate to make a patent right holder whole, a patent will not provide the proper incentives to invent and take risks to start a business or grow an existing business. As a consequence, the patent system will be less likely to spur growth in commercial activity that benefits society.

Compensation for willful infringement (*i.e.*, punitive damages) is based on the amount of compensatory damages awarded. If compensatory damages are inadequate, the amount of punitive damages, which are awarded on a discretionary basis by the people's court, may also not serve the purpose for which they are imposed, namely, as punishment for willful infringement. It is therefore critical, and especially for purposes of discouraging future infringement, that the compensatory damages (*i.e.*, not taking into account the punitive damages) fully compensate the plaintiff for damages incurred arising from the infringement.

Compensation for Willful Infringement (Punitive Damages)

Article 71 has been amended so as to recite that for willful infringement and where the circumstance is serious, the amount of compensation may be between one and five times the amount of compensatory damages.

As mentioned above, a patent right holder needs to be awarded compensatory damages that fully compensate for losses due to the infringing act. Where there is full compensatory relief, however, IPO's position is that punitive damages intended to punish the infringer for willful infringement should not be more than three times the compensatory damages, which is consistent with the standard in many other jurisdictions. Therefore, we recommend the following revision:

> *For willful infringement and where the circumstance is serious, the amount of compensation may be determined at an amount between one and ~~five~~* ***three*** *times the amount assessed in accordance with the above-mentioned method.*

Determining Willful Infringement

The term "willful infringement" is not defined in Article 71. As for determination of whether "the circumstance is serious." we note that the Supreme People's Court issued a draft *Opinions of the Supreme People's Court on Strengthening Punishment Intensity of Acts Infringing Intellectual Property Rights* ("Opinions," published on 15 June 2020 for comment) proposing to define in Article 15 elements where "the circumstance is serious" regarding infringement. We look forward to receiving further guidance in the final Opinions.

At a minimum, we believe where a defendant acts in bad faith in infringing a patent, such a situation constitutes "willful infringement and where the circumstance is serious" to warrant the increase in damages under Article 71. It has been our experience that more detailed guidance on "willful infringement" will be useful for courts and administrative agencies to determine whether an act of infringement is "willful." To this end, reference is made to IPO's letter of 2 February 2019 to the previous draft of the Patent Amendment, and we recommend that, either in Article 71 of the Patent Laws or in subsequent regulations or

interpretations, the following factors be enumerated for the court's consideration in determining willful infringement:

1. Whether the defendant acted in bad faith in its infringing activity;
2. Whether defendant acted consistently with the standards of behavior for its industry;
3. Whether defendant intentionally copied a product of plaintiff that is covered by the patent;
4. Whether defendant reasonably believed it did not infringe;
5. Whether defendant reasonably believed that the patent was invalid;
6. Whether defendant made a good-faith effort to avoid infringing the patent by, for example, attempting to design around the patent;
7. Whether defendant tried to cover up its infringement; and
8. Whether defendant reasonably relied on an opinion of counsel that its actions did not infringe the patent or the patent was invalid or unenforceable.

Accounting Books and Materials Relating to Infringement

Because of the importance of adequate compensatory relief, steps must be taken to ensure that "accounting books and materials relating to infringement" are made available by the infringer, and that guidance is provided as to the types of evidence the courts may consider in determining compensatory damages.

To that end, we recommend that two discretionary instances of the term "may" in Article 71 be amended to recite a mandatory "shall." Specifically, we recommend that the current language be amended as follows:

> *...the people's court ~~may~~ **shall** order the infringer to provide the accounting books and materials relating to the infringement.*
>
> *...the people's court ~~may~~ **shall** determine the amount of compensation by reference to the claims of the right holder and the evidence as submitted...*

The above two suggested changes reflect the fact that in order to determine how to compensate a patent owner for infringement, it is often necessary to determine the profits and sales of the infringer. Such an inquiry should not be discretionary, and making the inquiry mandatory would ensure consistency in application among courts.

Furthermore, we suggest that, either in Article 71 of the Patent Law or in subsequent regulations or interpretations, examples be provided of the types of evidence constituting "accounting books and materials relating to infringement" that the defendant must provide. Specifically, a list of examples may be enumerated such as: sales volumes, profit statements, retail sales, profits made from sales, and other such evidence.

We also recommend setting forth examples of other evidence (*e.g.*, submitted by the patent owner) from which courts may determine the amount of compensation when "the infringer fails to provide or provides false accounting books or materials" as set forth in Article 71. Specifically, such examples may include information such as:

- Public statements of the infringer about sales or commercial activity,
- Pricing of the infringer's products in stores or other venues,
- Market surveys,
- Statements in regulatory submissions to government agencies,
- Information made public through Initial Public Offerings (IPOs),
- Receipts from Customers,
- Retail sales information from third parties, and
- Other such information probative of the size and scope of the infringing activity.

**Article 75**

Article 75 as amended includes additional provisions relating to patent linkage. As a preliminary comment, IPO believes that patent linkage should be a separate and independent Article instead of being listed under Article 75 which is directed to patent infringement exemptions.

We recommend that, as with Article 42, the proposed patent linkage provisions be clarified so as to apply to both small molecule and biological drug products, and that further specificity be added as to the kinds of pharmaceutical drug patents that can be included in the Approved Drugs Patent Registration Platform.

We further propose that applicants filing Abbreviated New Drug Applications (ANDAs) be required to notify patentees, licensees, or holders of the marketing approval of the referenced product and/or provide certifications or statements related to infringement, and that there should be a provision allowing up to at least 45 days from the date when the patentee (or another stakeholder) is notified to institute a litigation and/or administrative action (instead of 30 days after the NMPA announces the submission of a marketing authorization application made by a generic drug applicant).

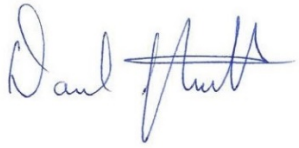
In addition, this article should also explicitly clarify that NMPA may not approve a pending marketing application that is the subject of a patent dispute resolution proceeding for the first 24 months of the judicial or administrative proceeding. As drafted, it is unclear whether suspension of regulatory review and approval process of the generic drug will automatically apply while the patent litigation or administrative action is pending. Furthermore, the draft is silent on whether the NMPA has discretion to grant the marketing authorization approval to the generic applicant if the patent challenge case has been pending for more than 9 months.

As mentioned earlier, currently there is no regulatory data protection in China. 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 new drug, IPO is concerned that the Draft Revision may be inadequate to protect innovators who expend significant resources in developing such data and undertake risks in the path towards drug development and approval.

We thank the Legislative Affairs Commission for its attention to IPO's comments submitted herein, and we welcome further dialogue and opportunity to provide additional comments.

We have enclosed this letter as translated herewith.

Sincerely,



Daniel J. Staudt
President

Attachment