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State Council Office of Legislative Affairs
P.O. Box 2067
Beijing, P.R. China
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国务院法制办公室
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Dear Sir or Madam:
尊敬的先生/女士：

The Pharmaceutical Research and Manufacturers of America ("PhRMA"), the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), INTERPAT and the Japan Pharmaceutical Manufacturers Association ("JPMA") offer the following comments on the Draft Patent Law of China ("Draft"). PhRMA, EFPIA, IFPMA, INTERPAT and JPMA are voluntary, nonprofit associations that represent the world's leading research-based pharmaceutical and biotechnology companies. Our members are dedicated to discovering valuable new medicines that enable patients to lead longer, healthier, and more productive lives.

美国药品研究与制造企业协会（PhRMA）、欧洲制药工业协会联合会（EFPIA）、国际制药商协会联合会（IFPMA）、国际创新药商协会（INTERPAT）和日本制药工业协会（JPMA）就中国《专利法（修订草案）》（下称"草案"）提出下述评论意见。PhRMA、EFPIA、IFPMA、 INTERPAT 和 JPMA 均是由世界领先的以研发为基础的制药和生物技术公司自愿结成的非盈利性协会。我们会员致力于发现有价值的新药，以延长患者生命，增进患者身体健康及提高生活质量。

I. General Comments
一，总体评论意见

We applaud the State Council, the State Council Office of Legislative Affairs and the State Intellectual Property Organization ("SIPO") for taking important steps in this Draft to increase protections for patent right holders and to streamline the enforcement process. This Draft makes important progress in these respects by providing for enhanced damages and seizure of infringing products and manufacturing tools in cases of willful infringement, lessening the patent holders' burden of proof on damages and increasing the cap for statutory damages from one to five million RMB. This Draft makes important strides in strengthening the system to protect the rights of patent holders.

我们赞赏国务院、国务院法制办公室和国家知识产权局在该草案中为加强对专利权人的保护及简化执法程序而采取的重要措施。这些重要进展体现在草案的下述规定之中，如在故意侵权情况下提高损害赔偿额并没收侵权产品和生产工具、减轻专利权人关于损害赔偿的举证责任、以及将法定损害赔偿额的上限从一百万元人民币提升至五百万元人民币。该草案在加强专利权人权利保护体系方面取得了重要进步。

We remain concerned, however, with certain aspects of the Draft and urge the State Council to consider addressing additional issues facing patent holders. Specifically, we urge careful consideration of the appropriate balance between protecting the rights of patent holders and measures to encourage fair competition in the market. China should ensure a protected scope of rights for patent holders within which these rights are deemed permissible until proved otherwise and not subject to undue scrutiny through the State's enforcement of anti-monopoly and fair competition law. Clear and balanced rules in this area will further China's goal of encouraging investment by pharmaceutical companies in innovative drug development. Related to this goal, the Patent Law should also avoid unnecessary interference with valid agreements between inventors and the businesses they partner with to develop their products.

但是，我们仍然对草案的某些方面感到担心，并恳请国务院考虑解决专利权人面临的其他问题。具体而言，我们恳请国务院认真考虑专利权人的权利保护与促进市场公平竞争的措施之间的适度平衡问题。中国应确保专利权人的权利保护范围受到保护，即在该权利保护范围之内，专利权人的所有权利均视为已被允许之权利，除非事后被证明相反；而且，该等权利不会受中国的反垄断与竞争法执法的不当审查。在该领域中采用明确、平衡的规则将有助于中国实现鼓励制药企业投资创新药品开发的目标。与此目标相关，专利法还应避免不必要地干涉发明人与企业就合作开发产品所达成的有效协议。

The Draft also should address other important issues, such as data supplementation during patent examination, certain dispute resolution mechanisms once a patent issues and patent term restoration. For example, the Draft should expand the availability of effective preliminary remedies to avoid infringement during the pendency of a dispute. It should establish a strong system for biopharmaceutical innovators to enforce their patent rights before an infringing party launches their drug on the market. In many cases, monetary damages will be insufficient to address the reputational and economic harm caused by the marketing of an infringing product.

草案还应解决其他重要问题，如专利审查期间的数据补充、专利授权后的争议解决机制及专利期限的延长。例如，草案应当扩大适用有效的临时救济措施以避免争议未决期间的侵权。草案应当建立一套强有力的体系，使生物制药创新企业能够在侵权方的侵权药品上市之前强制实施其专利权。在很多情况下，金钱损害赔偿并不足以弥补因侵权产品上市给生物制药创新企业所造成的名誉及经济上的损害。

II. Protection of Patent Rights and Anti-Monopoly Law
二，专利权保护与反垄断法

We support a balance between patent law and fair competition law. That balance should not, however, come at the expense of lawfully obtained patent rights.

我们支持在专利法和公平竞争法之间取得平衡。但是，该平衡不应当以合法取得的专利权为代价。

We are concerned about the potential breadth of Article 14 of the Draft, which forbids abuse of patent rights and harming public interests or unreasonably excluding or restricting competition. China's patent system already has built-in core principles that allow it to grant and protect patents for novel inventions in a way that considers the public interest. The patent system sets forth limits on patent rights as to their contents and their duration, articulates exceptions to those patent rights, and establishes conditions of patentability that prevent the grant of patents for inventions that lack novelty or an inventive step. Competition law should not be used to undermine China's WTO obligations to grant patents on new, non-obvious and useful inventions and should not impose undue constraints on patent rights.

我们担心草案第 14 条的适用范围过于宽泛，该条禁止滥用专利权损害公共利益或者不合理地排除、限制竞争。中国的专利制度已建立了授予和保护新颖发明的专利、并同时考虑公共利益的核心原则。该专利制度对专利权设置了内容和期限方面的限制，列明了专利权的例外规定，并规定不得为缺乏新颖性或创造性的发明授予专利的专利申请条件。竞争法不应被用于减损中国就具备新颖性、非显而易见性、有用性的发明授予专利的 WTO 义务，且不应对专利权施加不当的限制。

Furthermore, the patent system requires that patent applicants publish their patent applications. This publication requirement furthers the development of innovation and can have real, concrete benefits for technological advancement in China and, in the healthcare industry, for Chinese patients. International practice demonstrates that a patent holder should be rewarded for investing in new technology and for publishing its invention by granting it the right to exclude others for a limited duration and to license or transfer its patent at its discretion for the claimed invention. This rule incentivizes not only innovation, but also fair competition.

而且，中国专利制度要求专利申请人公开其专利申请。这项公开要求将进一步促进创新，给中国的技术进步带来切实、具体的好处，并在医疗健康领域使中国的患者受益。国际实践表明，专利权人投资新技术并公开其发明应当受到奖励，此种奖励允许其在一定期限内排除其他人，并可就其申请的发明自由许可或转让。这项制度鼓励的不仅仅是创新，还有公平竞争。

Therefore, we ask the State Council and SIPO to remove Article 14 and to clarify that China's developing body of fair competition anti-monopoly law will not be used to interfere with patent rights granted under the Patent Law. This approach is in accordance with the Anti-Monopoly Law principle that enforcement of fair competition policy should not interfere with intellectual property rights.

因此，我们恳请国务院和国家知识产权局删除草案的第 14 条规定，并澄清，中国的竞争与反垄断法执法机构将不会干预依据中国专利法取得的专利权。该做法与中国《反垄断法》规定的实施公平竞争政策不应干预知识产权权利的原则是一致。

III. Protection of Inventor Remuneration Arrangements
三，保护发明人报酬的安排

Businesses that invest in research and development in China need certainty that the arrangements they make with their employed inventors will be controlling. While we support well-defined protections for inventor remuneration, these protections should not be used in ways that undermine certainty or damage the flexibility companies need to incentivize their employees and partners and to continue to develop innovative technology in China.

在中国进行研发的企业需要确定性，即他们与其雇佣的发明人之间的安排具有决定性效力。尽管我们支持对发明人报酬的保护进行合理界定，但这些保护措施不应减损上述研发企业所需的确定性，或者限制企业在激励其员工及合作方并继续推动中国的技术创新方面所需的灵活性。

With those principles in mind, we urge the State Council and SIPO to ensure the Draft recognizes and safeguards valid arrangements between inventors and companies. We recommend clarifying that businesses are permitted to incentivize their employees and partners to innovate and operate in the most beneficial manner for their businesses. With respect to Article 6, we suggest the State Council and SIPO remove the proposed amendment to the final paragraph. For inventions made by taking advantage of the material and technical means of an entity, the right of patent application correctly belongs to the entity. In Article 16, we recommend clarifying that the entity required to "pay the inventor or designer" is the entity that employed the inventor or designer at the time the invention was made.

考虑到这些原则，我们恳请国务院和国家知识产权局确保草案认可并保护发明人与企业之间达成的有效安排。我们建议澄清，允许企业激励他们的员工和合作方，以使企业能够以最有利于企业发展的方式进行创新和运营。关于草案第 6 条规定，我们建议国务院和国家知识产权局删除针对该条最后一款的修订内容。就利用单位的物质和技术条件所完成的发明而言，申请专利的权利理应属于单位。关于第 16 条规定，我们建议澄清，应"对发明人或者设计人给予奖励和报酬"的单位系发明完成时雇佣该发明人或设计人的单位。

The entity that employed the inventor or designer at the time the invention was made and the "entity to whom the patent is granted" may not be the same. For example, contract research organizations ("CRO") in China routinely develop technologies under contract to third parties. Requiring a third party to which the patent is granted or assigned to pay remuneration to inventors or designers employed by a CRO after the third party has paid the CRO to conduct inventive activities under commissioned technology development contracts would create confusion and uncertainty and could harm China's vibrant contract research industry.

发明完成时雇佣该发明人或设计人的单位与"被授予发明专利的单位"可能不是同一主体。例如，合同研究组织（下称"CRO"）在中国经常根据合同约定为第三方提供技术研发服务。在委托技术开发合同项下，CRO 收取第三方的费用，并根据委托技术开发合

同开展发明行为；在此情形下，要求被授予或受让专利的第三方为由 CRO 雇佣的发明人或设计人支付报酬将引起混淆和不确定，且将损害中国生机勃勃的合同研发行业。

IV. Scope of Patent Re-Examination Board Review
四，专利复审委员会的审查范围

We are concerned by provisions at Articles 41 and 46 of the Draft related to the scope of Patent Re-Examination Board ("PRB") review. While we understand SIPO's Patent Examination Guidelines currently provide some limited guidance regarding the PRB's review of patents for compliance with the Patent Law, phrases such as "when necessary" and "other provisions set forth under this law" are unclear and appear to provide overly broad authority to the PRB to examine issues not raised in an appeal. For these reasons, we recommend that the State Council and SIPO remove the language added to the second paragraph of Article 41 and the first paragraph of Article 46 or provide clear guidance in the Patent Law regarding the scope of the PRB's review.

我们对草案第 41 条和第 46 条项下规定的专利复审委员会的审查范围感到担心。尽管我们知道国家知识产权局的《专利审查指南》就专利复审委员会审查专利是否符合专利法要求提供了一些有限的指导，但诸如"必要的时候"及"本法有关规定的其他情形"等词语很不明确，且可能赋予专利复审委员会过于宽泛的权力以至于审查相关申请中未提出的事项。基于这些原因，我们建议国务院和国家知识产权局删除草案第 41 条第二款项下的新增的修订内容以及第 46 条第一款内容，或者在专利法中就专利复审委员会的审查范围予以明确规定。

We recognize the priority the Patent Law places on "timely" PRB examination of requests in Article 46. Timely action is equally important for notification of decisions to the patent applicant in Article 41 and to the petitioner and patentee in Article 46. We suggest the State Council and SIPO ensure the Patent Law reflects the importance of prompt notice to the parties to a PRB appeal.

我们赞同专利法要求专利复审委员会对第 46 条项下的宣告专利权无效的请求进行"及时"审查的重要性。及时性对于向第 41 条项下的专利申请人以及第 46 条项下的请求人和专利权人告知相关决定的通知同样重要。我们建议，国务院和国家知识产权局应确保专利法能够体现专利复审委员会迅速通知相关当事方的重要性。

V. Data Supplementation and the Process for Examination and Approval of Biopharmaceutical Patent Applications
五，关于生物制药专利申请的数据补充与审批程序

China's revision of its Patent Law provides an important opportunity to clarify that patent applicants may submit additional data after the filing date of the initial patent application. This approach would enable the filing of patent applications in a timely manner, while also allowing patent applicants to supplement those applications with experimental data developed after filing, consistent with the drug development process.

此次专利法修订为澄清专利申请人在提交专利初步申请之后仍可提交补充数据提供了一个重要契机。该做法将使专利申请更加及时，同时允许专利申请人补充在申请提交之后获得的试验数据，这与药品的研发流程相一致。

By allowing data supplementation, China would provide greater and much-needed certainty for innovative biopharmaceutical companies seeking to obtain and maintain patents on their products in China and encourage the development of innovative medicines in China. Permitting such data supplementation will also help SIPO's patent examination practices conform to the well-functioning practice of many other countries, such as the United States, the European Union, Japan and Korea. Moreover, including these changes in China's Patent Law would also enable China to implement its December 2013 commitment under the U.S.-China Joint Commission on Commerce and Trade to allow patent applicants to submit additional biological data after filing their applications.

通过允许补充提交数据，中国将为致力于在中国获得并保有专利产品的创新生物制药企业提供渴望已久的更大的确定性，并促使他们在中国进行创新药品的研发。允许补充数据也将有助于国家知识产权局的专利审查实践与许多其他国家的行之有效实践相接轨，比如美国、欧盟、日本及韩国。而且，在专利法中纳入这些修订内容，也将有助于中国履行其在 2013 年 12 月中美商贸联委会上作出的关于允许专利申请人在提交申请之后补充提交生物数据的承诺。

Since the December 2013 commitment, SIPO sometimes has permitted submission of post-filing data to rebut insufficiency rejections under Article 26.3, but also has increased rejections for lack of inventive step under Article 22.3. The conditions under which supplemental data may be submitted are not always clear. Even though SIPO guidelines provide for supplementation in some limited circumstances, such as if the supplemental data is for the purpose of corroborating facts or statements set forth in the original application, too often supplemental data is not accepted even in those limited circumstances. Neither the Patent Law nor relevant regulations and rules articulate a clear and consistent standard in this respect. This is an opportunity to clarify the conditions for submission of post-filing data.

自 2013 年 12 月中国作出上述承诺以来，国家知识产权局已允许申请人在申请提交之后就第 26.3 条项下规定的因公开不充分而驳回的申请进行反驳，但基于第 22.3 条项下规定的因缺乏创造性而被驳回申请的情况也有增加。在何种情形下允许补充提交数据并不总是很明确。尽管国家知识产权局的指南允许在一些有限的情形下进行数据补充，如为证明原申请中的事实或陈述而补充提交的数据等，但即使在这些有限的情形下补充提交的数据也经常不被接受。在这方面，无论是专利法，还是其他相关法规规章均未规定明确、一致的标准。此次修订是澄清关于申请提交后补充数据的条件的很好契机。

China's limitations on submitting supplemental data are also inconsistent with how innovative medicines are developed in practice. Developing a new treatment is a long, multi-year process – taking, on average, 10-15 years – that requires multi-phase trials often occurring on a global scale. These trials generate important data about the safety and effectiveness of a medicine under specific conditions, which inform its overall development, sometimes even after

approval by a drug regulatory authority. This process ensures that the safest, most effective version of the medicine ultimately reaches patients.

中国限制提交补充数据的做法亦不符合创新药品研发的实践。开发一种新疗法是一项长期、多年的过程（平均耗时 10 至 15 年），并需要在全球范围内进行多期的试验。这些试验获得的有关特定条件下药品的安全性和有效性的重要数据贯穿于整个研发过程，有时甚至在取得药品监管机构批准之后获得。这些过程确保患者能够最终获得最安全、最有效的药品。

The benefits of new treatment, particularly in humans, often are not fully demonstrated when the drug is first discovered and has not yet gone through the clinical development process. However, patent applicants generally are required to submit their applications and disclose their inventions before those benefits are fully demonstrated to protect their rights. Disclosure of the invention is beneficial for the public and securing patent protection early during the research and development process incentivizes innovation and the considerable investment necessary to complete clinical development.

新疗法的疗效，尤其是对于人类而言，在首次发现该药品并未经临床检验之前通常并未经充分证明。但是，专利申请人通常被要求在这些疗效被充分证明、从而得以保护他们的权利之前提交专利申请并披露他们的发明。披露发明有利于公众利益，而尽早在研发过程中对专利进行保护有助于激励创新及鼓励巨额资金的投入以完成临床研发。

To meet the patentability standards under the Patent Law and permit an applicant to fully protect its invention, some mechanism is needed that permits patent applicants to supplement their initial patent application filings. Specifically, applicants should be permitted to submit supplemental data to confirm that the claimed invention is novel, useful and contains an inventive step, and to confirm and further support the statements and facts already disclosed in an applicant’s patent application.

为满足专利法规定的专利性标准并允许申请人充分保护其发明，允许专利申请人对其初步申请进行补充的制度很有必要。特别是，申请人应被允许提交补充数据，确认其申请的发明是新颖、实用且具有创造性，并确认及进一步支持其已在专利申请中披露的陈述和事实。

We respectfully request, therefore, that the State Council and SIPO reconsider this issue. We ask the State Council to include language in the Patent Law that clearly delineates when SIPO will accept supplemental data.

因此，我们恳请国务院和国家知识产权局重新考虑该问题。我们建议国务院在专利法中明确规定，国家知识产权局何时将接受补充数据。

VI. Effective Patent Enforcement Mechanisms
六，有效的专利执行机制

We applaud the State Council and SIPO for the significant efforts in this Draft to increase deterrents to infringement, including increased penalties and more flexible standards of burdens of proof for economic damages. We also recognize that China has gradually improved its system for obtaining preliminary relief. For example, China has permitted preliminary injunctions for patents since 2000 and, as of 2012, has expanded rights to preliminary injunctions to include access in trade secret cases. We urge China to continue to expand these and other mechanisms that provide for the early resolution of patent disputes before infringement causes irreparable damage.

我们赞赏国务院和国家知识产权局在草案中关于加强对侵权行为的威慑措施，包括提升处罚幅度以及就经济损失的举证责任采取更为灵活的标准。我们也注意到，中国已逐步完善关于临时救济的制度。例如，中国自 2000 年开始允许对专利侵权行为采取临时禁令；截止 2012 年，该临时禁令救济措施已扩展至商业秘密案件。我们建议中国继续扩展这些在侵权行为造成无法恢复的损害之前即尽早解决专利纠纷的救济机制以及其他救济机制。

It is important to have a system in place that prevents the marketing of a potentially infringing pharmaceutical product prior to the resolution of any patent disputes. If a generic drug company receives approval and actually begins to market a drug that infringes an innovator's patents, the damage to the innovator may be irreparable, even if the innovator later wins its patent dispute. For this reason, a number of countries have linked the drug approval process to patent protection in some way as a safeguard to prevent agencies from contributing to infringement by granting approval while the parties are resolving the patent dispute. Channels for early dispute resolution also reduce the costs of patent suits and increase predictability in the market for all stakeholders.

建立一套防止可能侵权的药品在专利纠纷解决之前上市的制度尤为重要。如一家仿制药品企业获得批准并实际开始上市销售一种侵犯发明人专利权的药品，即使发明人之后赢得了专利纠纷，该行为对发明人造成的损害可能是无法弥补的。基于此，很多国家已将药品审批程序与专利保护联系起来，以确保审查机关不会在相关当事人正处于专利争议解决过程中授予上市许可、从而助长侵权行为。尽早解决纠纷的方式也将减少专利诉讼的成本，并提升市场上所有利益相关方的可预期性。

We recognize China has established some limited linkage between the drug approval process and patent protection. This should be preserved and improved to encourage biopharmaceutical innovation. To better enable innovators to enforce their rights in a timely manner, there should be clear mechanisms in place to alert generic drug companies to the patent status of innovative medicines and to alert innovators to the filing of potentially infringing applications for marketing approval. Furthermore, patent holders must be permitted sufficient time to resolve or at least to engage in meaningful dispute resolution prior to the marketing of the generic or biosimilar product.

我们注意到，中国已经在药品审批程序与专利保护之间建立了一些有限的联系。这些联系应予保留并加以完善，以促进生物制药创新。为使发明人能够更及时地行使其权利，应有明确的机制提醒仿制药品生产企业注意创新药品的专利状态，并提醒发明人存在可能侵犯他们专利权的上市审批申请。而且，在仿制药品或生物仿制药品上市之前，应给予专利权人充足的时间解决争议或者至少进行有意义的争议解决尝试。

We urge the State Council and SIPO to further consider these factors and to take appropriate measures to afford biopharmaceutical innovators the opportunity to prevent and resolve patent disputes before a potentially infringing product is marketed.

我们恳请国务院和国家知识产权局进一步考虑上述因素，并采取适当措施，给予生物制药创新人在可能侵犯其专利权的药品上市之前、防止并解决专利纠纷的机会。

VII. Patent Term Adjustment and Restoration
七，专利期限调整及延长

The Draft is also an opportunity for the State Council and SIPO to bring China's Patent Law in line with emerging global and regional norms and the practices of other leading innovative economies by amending Article 42 to provide for adjustment and restoration of the patent term to compensate for unreasonable delays that occur in granting patents and for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

本次草案修订也为国务院和国家知识产权局在专利期限延长方面将中国的专利法与其他全球及地区最新的主流创新经济体的标准与实践相接轨提供了良好契机，即修订第 42 条并规定，允许对专利期限进行调整及延长，以弥补在授予专利的过程中所产生的不合理迟延以及因上市审批程序所导致的有效专利期限的不合理减少。

While SIPO is working to improve the efficiency of patent examination, including through work sharing arrangements with other leading patent offices, and the China Food and Drug Administration is taking steps to reduce drug registration delays, the State Council and SIPO should ensure incentives provided through China's Patent Law reflect international best practices. Unreasonable patent office and marketing approval delays undermine incentives for international and Chinese inventors to develop and launch innovative biopharmaceuticals in China.

当下国家知识产权局正努力提高专利审查的效率，包括通过与其他主要的专利办公室安排工作分工，同时，国家食品药品监督管理总局也正采取措施减少药品注册的迟延。国务院和国家知识产权局应确保中国专利法项下规定的激励措施能够反映最佳国际实践。因专利审查和上市许可审批所导致的不合理迟延将损害国际和中国发明人在中国进行创新生物制药研发的积极性。

VIII. Conclusion
八，结论

Our associations and member companies appreciate this opportunity to provide feedback to the State Council and hope to establish a closer, sustained dialogue with the State Council on these important issues. As always, our associations stand ready to discuss practical and actionable suggestions, based on our international experience, to help the State Council achieve its reform objectives. In addition, we encourage the State Council to contact us at any time should it have further questions about the viewpoints or the concepts discussed in these comments. Please contact Brendan Barnes (brendan.barnes@efpia.eu), Brendan Shaw (b.shaw@ifpma.org), Peter I. Dolton (Peter.Dolton@btinternet.com), Yoichi Okumura (yoichi.okumura@takeda.com) and Chris Moore (CMoore@phrma.org).

我们协会及会员企业非常感谢能有此机会向国务院提交反馈意见，并期望与国务院就上述重要事宜建立更为紧密、持久的对话机制。如同以往一样，我们协会将基于我们的国际经验，随时准备与国务院探讨切实可行的建议，以协助国务院实现改革目标。此外，如国务院就上述评论意见中的观点或概念有进一步疑问，我们欢迎国务院随时与我们联络。来函请联络 Brendan Barnes (brendan.barnes@efpia.eu), Brendan Shaw (b.shaw@ifpma.org), Peter I. Dolton (Peter.Dolton@btinternet.com), Yoichi Okumura (yoichi.okumura@takeda.com) 及 Chris Moore (CMoore@phrma.org).

Sincerely,
最诚挚的

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