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Comments of PhRMA, EFPIA, IFPMA, INTERPAT and JPMA on the Draft Patent Examination Guidelines
PhRMA、EFPIA、IFPMA、INTERPAT 和 JPMA 关于《专利审查指南修改草案（征求意见稿）》的意见

Dear Sir or Madam:
尊敬的先生或女士：

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) (collectively "the Associations") are pleased to submit these comments to the State Intellectual Property Office ("SIPO") on the draft Patent Examination Guidelines ("Draft Guidelines").

美国药品研究与制造商协会 (PhRMA)、欧洲制药工业协会联合会（EFPIA）、国际制药商协会联合会（IFPMA）、INTERPAT 和日本制药工业协会（JPMA）（统称"协会"）欣然就《专利审查指南修改草案（征求意见稿）》（"《指南修改草案》"）向国家知识产权局（"SIPO"）提交以下意见。

The shared mission of the Associations is to support public policies that encourage the discovery and development of innovative medicines for patients around the world. Many of our member companies operate globally and have substantial research, development, and manufacturing operations in China. We wish to continue to partner with SIPO on these and

other efforts in order to support China's sustainable and innovation-driven pharmaceutical and biotechnology industry development goals.

协会的共同使命是支持旨在鼓励为全世界的患者探索并开发创新性药物的公共利益政策。我们的许多成员公司在全球营运，且在中国拥有大量研发和生产业务。我们希望继续在这些和其他工作上与国家知识产权局合作，以支持中国可持续性的、以创新为驱动的制药和生物科技产业的发展目标。

We remain very grateful for these and other opportunities to comment on these critical administrative efforts and to offer international expertise and guidance.

我们十分感谢有此机会和其他机会对这些关键行政管理工作提出意见，并提供国际专业知识和建议。

I. General Comments
一般意见

The Associations would like to express support for certain provisions in the Draft Guidelines. We are particularly encouraged to see the revisions related to data supplementation, which encourage the development of innovative medicines. We also support other amendments in the Draft Guidelines, including measures that can aid in protecting patent rights. We appreciate that SIPO has taken international experience into account when drafting these revisions, and we encourage it to do so as it further develops them.

协会想表达对《指南修改草案》中某些条款的支持。特别是，看到与数据补交相关的、鼓励开发创新性药物的修订，我们深感鼓舞。我们还支持《指南修改草案》的其他修订，包括可有助于保护专利权的措施。国家知识产权局在进行这些修订时吸取国际经验，对此我们表示赞赏，并且我们鼓励国家知识产权局在进行进一步修订时，也同样参考国际经验。

II. Data Supplementation
数据补交

We applaud SIPO for the amendment to Section 3.5 to require examiners to "examine the post-filing experimental data submitted by the applicant." This amendment appears to be intended to implement China's commitment, made during the U.S.-China Joint Commission on Commerce and Trade in December 2013, to permit patent applicants to file additional data after the application filing date. This amendment will permit timely filing of applications but also allow applicants to submit additional information consistent with the drug development process. We believe it to be a critical reform to meet China's goal of encouraging drug innovation.

我们对国家知识产权局对第 3.5 条的修订，即要求审查员"审查申请日之后补交的实验数据"表示赞同。该修订似乎旨在兑现中国在 2013 年 12 月的美中商贸联合委员会期间所作出的承诺，即允许专利申请人在提交专利申请后提交额外的数据。该修订将准许及时提交

申请，但亦允许申请人提交符合药物开发流程的其他信息。我们认为，这是中国为达到鼓励药物创新的目标所作出的重大改革。

The Associations view the amendment to Section 3.5 as an important step toward implementing a clear and consistent standard that permits biopharmaceutical manufacturers to submit additional data to confirm that the invention is novel, useful and contains an inventive step. The submission of supplemental data will also support and confirm statements that have already been disclosed in the patent application. We assume that by requiring the examiner to examine supplemental experimental data, this new provision will be implemented in such a way that the supplemental data can be relied upon to successfully respond to an examiner's rejection and to expand on the disclosure provided in the patent application.

对于第 3.5 条的修订，协会将其视为实施清晰且一致标准的重要步骤，该标准将允许生物制药企业提交额外数据，以确认发明具有新颖性和实用性，并包含发明步骤。提交补充数据亦将支持并确认已在专利申请中公开的声明。我们设想，通过要求审查员审查补交的实验数据，该新条文将以这样的方式实施：即可以依靠补交数据成功回应审查员的驳回，以及详细阐述专利申请中所提供的披露。

Most importantly, this reform can encourage the development of life saving medicines in China for which it may not be possible to provide further evidence of the demonstrated benefit until later in the development process. Without the ability to secure patents on innovative medicines, drug manufacturers would not have the incentives necessary to undertake the multi-year, multi-billion dollar investment required to develop new medicines.

最为重要的是，此项改革可以鼓励在中国开发救命药，因为对于某些药物，在开发流程进入后期阶段前，可能无法提供进一步证据证明所述的益处。如果没有能力保护创新药物的专利，药品生产企业不会有动力为开发新药而投入所需的长达数年的时间及多达数十亿美元的资金。

The foregoing notwithstanding, we have two concerns with the data supplementation amendment as currently proposed. First, the amendment to Section 3.5 would make the data supplementation approach applicable only to "Sufficiency of Disclosure of Chemical Inventions." We believe the same approach should be taken to the examination of other patentability issues, such as inventive step, and therefore should be incorporated into Section 6, Chapter 10 of Part II as well.

尽管对前述修订表示赞同，我们仍对目前建议的数据补交之修订有两个顾虑。 首先，对第 3.5 条的修订会使该数据补交方法仅适用于"对化学发明的充分公开"。我们认为，在审查其他专利性问题（如创造性步骤）时，亦应采取相同的方法，因此该方法亦应被纳入第二部分第十章第 6 条。

Second, we are concerned that certain language in the proposed amendment may be interpreted too narrowly by SIPO examiners, resulting in less patent incentives for new medicines in China and thereby harming Chinese patients. Specifically, the amendment permits data supplementation only where "the technical effect to be proved by the supplemented

experimental data shall be one which can be derived by a person skilled in the art from the disclosure of the patent application." If this is interpreted so as to require the application to already disclose or demonstrate the precise technical effect to be proven by the offered supplemental data, the result would be that supplemental data is rarely accepted. This result can be avoided by incorporating more detailed guidance in the Guidelines to make it explicit that the requirements are in line with those commonly used in other countries. For example, the European Patentability Examination Guidelines (Section 11) provide that supplemental data will be accepted if it proves effects that "are implied by or at least related to the technical problem initially suggested in the originally filed application."[1]

其次，我们担心国家知识产权局的审查员可能会过于狭义地解释建议修订中的某些文字，导致对中国新药专利的激励性降低，从而伤害中国的患者。特别是，修订仅允许在"补交实验数据所证明的技术效果应当是所属技术领域的技术人员能够从专利申请公开的内容中得到的"情况下补交数据。 如果这被解释为要求申请已经公开或说明所提供的补交数据将证明的精确技术效果，会导致补交数据极少被接纳。通过在指南中纳入更为详细的指导，明确说明该要求与其他国家普遍使用的要求一致，可避免该结果。 例如，《欧洲专利性审查指南》(European Patentability Examination Guidelines)（第 11 条）规定，如果补交数据证明"初始提交的申请中最初建议的技术问题所暗示的效果或至少与之相关的效果"[2]，则将接纳补交数据。

In implementing this provision, we urge SIPO to keep these considerations, goals and benefits in mind and provide additional guidance consistent with them.

在实施该条文时，我们恳请国家知识产权局考虑这些注意事项、目标和益处，并提供与之相符的额外指导。

[1] Available at http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/$File/guidelines_for_examination_part_g_en.pdf.

[2] 载于 http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/$File/guidelines_for_examination_part_g_en.pdf。

III. Conclusion
结论

The Associations are grateful for this opportunity to submit comments, and look forward to working with SIPO not only on the Draft Guidelines but also on other legislative and enforcement efforts that are central to the establishment of an effective framework for patenting inventions and enforcing those patent rights. We support provisions that provide greater certainty and protection to patent rights. Should you have any questions about these or other comments, please reach out to Chris Moore (cmoore@phrma.org) or Jennifer Osika (josika@phrma.org).

协会感谢有此机会提交意见，并期待与国家知识产权局的合作并不限于《指南修改草案》，还能延伸到对于建立有效的发明专利申请框架和强制执行这些专利权至关重要的其他立法和执法工作，与国家知识产权局合作。我们支持对专利权提供更大确定性和保护力度的条文。如您对这些或其他意见有任何疑问，请联系 Chris Moore (cmoore@phrma.org)或者 Jennifer Osika (josika@phrma.org)。

Sincerely,

此致

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