By Electronic Submission

To the State Intellectual Property Office,

The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide comments to the State Intellectual Property Office (SIPO) of the People's Republic of China concerning the October 2011 *Draft Measures for the Compulsory Licensing of Patents*.

BIO is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. States and 32 countries around the world. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics.

The majority of BIO's members are small and medium sized enterprises that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their patents to generate investment to take their technologies to commercialization. More and more, BIO's members are looking outside the U.S. as they expand their markets and R&D and commercialization efforts.

China, in particular, is viewed by BIO as a key market. Many of BIO's more established companies already do business in China, and over recent years several of BIO's small and medium sized members have also expressed an interest in doing business there. Earlier this year, BIO hosted a mission to Beijing and Shanghai where 13 CEOs of small and medium sized biotechnology companies met with key research parks and government officials. Furthermore, in October BIO hosted its first ever BIO China event, which attracted over 700 biotechnology professionals from China and other parts of Asia along with professionals from the U.S. and Europe.

BIO's members were heartened to learn more about China's recently announced 12th 5-Year Plan which provides considerable support for biotechnology innovation and aims to support both the development and manufacture of new biotechnology products. This 5-year plan holds substantial promise to elevate China's position and leadership in the industry. In accordance with this 5-year plan, many in China have recognized the importance of intellectual property protections, in particular with respect to biotechnology. China's leaders understand that inappropriately expansive compulsory licensing regime poses great risk to the fulfillment of the promise of the 5-year plan and to Chinese innovative biotechnology companies as they invest significant resources in the development of their products. Accordingly, legislation and regulation that have the potential to impact the biotechnology sector should be considered carefully by the Chinese government to ensure that they do not negatively impact China's burgeoning biotechnology sector. In this regard, BIO's members wish to make the following observations and comments on the recently issued *Draft Measures for the Compulsory Licensing of Patents.*

Draft Measure Comments

The *Draft Measures* aim to implement Articles 48-58 of China's Patent Law. BIO's members appreciate the Chinese government's effort to provide greater clarity for all interested parties regarding the issuance of compulsory licenses in China. Our members also appreciate the recognition by the Chinese government that robust patent protections will incentivize an innovative biotechnology sector in China. However, this can only be achieved with policies that ensure rare and narrow use of compulsory licenses only in extreme circumstances. This will ensure an appropriate balance is struck.

Our members have highlighted certain parts of the Draft Measures which require careful consideration. We respectfully offer the following specific suggestions.

- The term "patentee" is used throughout the Draft Measures. BIO recommends that the Draft Measures include a definition of "patentee" that includes those that are "right holders" to account for circumstances where the patent is exclusively licensed.

- BIO recommends that the scope of the following terms be better defined. They include the phrase "legitimate reasons" in Article 5, "public interests" in Article 6, and "public health" in Article 7. Defining these terms in greater detail would help provide clarity for industry to understand the terms and process for issuing a compulsory license.

- In Article 5, it should be clarified that importation of a product subject to a patent for supply of the Chinese market shall be considered exploitation of the patented invention.

- Article 6 should be clarified to explain that a declaration by the Chinese government of the existence of circumstances of a national emergency or an extraordinary state of affairs must precede the use of this authority for compulsory licensing. In addition, the reference to "purposes for public interests" should be clarified to explain that these circumstances are limited to narrow situations that do not affect the legitimate commercial interests of the patent owner, such as to enable uses of the patented invention to enable government operations.

- Article 7 (b) allows for compulsory licenses for the needs of "developed" WTO members. But neither TRIPS nor the Doha Declaration imagines an expansion of compulsory licenses to be used in China for permit manufacture and export of products to developed countries like the United States or Europe. BIO respectfully submits that the provisions of Articles 7(a) and (b) be limited to conform to existing treaty and trade agreements obligations to ensure that these provisions are used appropriately.

- BIO recommends clarification of Article 8's terms "major technological advancement" and "remarkable economic significance" so that government and industry can better understand when such circumstances may occur. In addition, it should be made clear which agency will make these determinations, what technical expertise is required to carry out the task and what standards-- national or international-- are to be employed. Finally, BIO suggests that the measures clarify that a prior patentee requests a compulsory license from a later patentee to ensure compliance with obligations of Article 31 of the TRIPS Agreement. We also respectfully recommend that the article make clear that if a later patentee is not subject to a compulsory license then the prior patentee also not be subject to one – this will conform the measure to the obligations of the TRIPS Agreement, Article 31(l).

- BIO recommends that Article 11 include additional provisions to clarify situations that involve patents that have not been worked for 3 years after grant or 4 years after filing. Our members suggest the following:

"In considering the compulsory license application under Article 48(1), SIPO shall also take into account, --

(i) steps taken by the patentee to prepare for importation or domestic manufacture of the patented invention, or to prepare for use of the patented invention within China;

(ii) the nature of the invention and the measures already taken by the patentee or any licensee to make full use of the invention;

(iii) whether compliance with administrative or regulatory requirements has limited the ability of the patentee or any licensee to make full use of the invention;

(iii) the ability of the applicant to work the invention to the public advantage;

(iv) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

- Article 16 requires the patentee to respond within a "prescribed time period." We recommend that the time period be defined within the Article, and be not less than 90 days.

- Article 17 calls for on-site inspections if necessary, but does not make clear how SIPO determines if an inspection is necessary. It would be helpful for the measure to indicate whether the requestor or the patentee need to request an on-site inspection or whether the decision will be made only on the materials submitted.

- Article 18 requires the Office to notify interested parties not later than 7 days prior to a hearing date. We submit that this is a very short period of time to prepare for a hearing. We also note that if the compulsory license request is based on a national emergency or is in the public health interest, the law permits SIPO to proceed without providing a hearing concerning the license application. However, in all other circumstances, a hearing is to be provided. In those non-emergency situations, there is no reason to impose such a short period for notice. BIO respectfully submits that parties should be provided more time (such as 60 days in advance of the hearing) to enable them to prepare adequately for the hearing.

- BIO recommends that Article 21 (c) be revised to ensure that the scope, term and other conditions of the compulsory license are tailored to actual requirements justifying the grant of the license, as is required by Article 31 of the TRIPS Agreement.

- We note that Article 22 (a) does not provide an authority to determine the amount of drug manufactured under a compulsory license. While it specifies not exceeding the demand of the "importing party," clarification of what constitutes an "importing party" and ensuring that the "importing party" has the appropriate technical expertise to make this determination is important.

BIO recommends that Article 22 (b) include strengthened anti-diversion measures as follows:

"the pharmaceuticals manufactured under a compulsory licensing shall bear a label or mark stating that such pharmaceuticals are manufactured under a compulsory license for export to the relevant market only; on the feasible conditions and without any prejudice to the price of such pharmaceuticals, special colors or shapes shall be used for the pharmaceuticals, or otherwise special packing shall be used;

(a) if the product(s) covered by the compulsory license is patented in the importing country cited in the application, the product shall only be exported if those countries have issued a compulsory license for the import and sale of the product

(b) the entity obtaining such license shall keep complete and accurate books and records of all quantities of product manufactured and of all dealings. The entity shall make these books and records available on request to an independent person agreed by the parties, for the sole purpose of checking whether the terms of the license, and in particular those relating to the final destination of the products, have been met.

(c) the entity obtaining such license shall be required to provide proof of export of the product, through a declaration of export certified by the customs authority concerned, and proof of importation or marketing certified by an authority of the importing country, and shall retain such records for at least three years. Upon request these records must be supplied to the competent authority;

(d) the entity obtaining such license shall be responsible for the payment of adequate remuneration to the patentee as determined by SIPO to account for the economic value of the use that has been authorized under the license to the importing country concerned."

- We recommend that Article 22 (c) require that the licensee of a compulsory license report to the patentee the number of lots manufactured and shipped so that the patentee can monitor and track the manufacture and use of products under the compulsory license. In addition, Article 22 only applies to compulsory licenses granted under Article 50 of the patent law; BIO suggests that the Chinese government consider whether such provisions should apply more generally. It is our view that the patentee is entitled to monitor and track the manufacture and use of compulsory licensed products.BIO recommends that Article 24 affirmatively state that royalties to the patentee are required upon grant of a compulsory license. We suggest that a Chinese government agency with appropriate expertise automatically consider the appropriateness of a royalty. Moreover, we believe that the patentee should be able to request royalty payment subsequent to the grant of a compulsory license and that the Chinese government should consider some minimum royalty rate for typical industries.

- Articles 25 to 29 further address royalties. BIO recommends that these articles include language that requires SIPO to consider international standards and norms and provide a hearing as requested by either party.

- In considering the appropriateness of the royalty fee under Article 57 of the Patent Law, the Claimant shall provide evidence to SIPO proving that the Claimant has already requested the

entity obtaining the license to provide a royalty but failed to obtain a royalty agreement within a reasonable time.

In conclusion, BIO appreciates the opportunity to engage with SIPO to discuss these Draft Measures that will greatly affect innovative biotechnology companies.

Sincerely,

/s/

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