
The US-China Business Council (USCBC) and its member companies appreciate the opportunity to submit comments on the draft Measures for the Compulsory Licensing of Patents, issued on October 12, 2011. USCBC believes that the call for comments represents a positive and constructive effort by the State Intellectual Property Office (SIPO) to provide a competitive environment for US companies doing business in China. SIPO’s efforts will and increase the level of transparency and communication between Chinese regulators and US companies. USCBC member companies are committed to serving the China market, and many of our member companies have had extensive experience both in China and internationally addressing intellectual property rights and licensing issues. Their expertise and contributions toward regulatory policies in these areas will result in a stronger regulatory environment that encourages innovation and technological advancements.

USCBC represents roughly 240 US companies conducting business in China, all of which have a strong interest in the protection of intellectual property rights. Full and robust protection of intellectual property rights—including patents—is one of the most important foundations of an innovative economy, as such IP protections help to foster innovation by providing inventors with a clear path to commercialize and profit from their inventions. Compulsory licenses, while providing opportunities to broaden the usage of patents, necessarily curtails such patent rights. Given the potential of compulsory licensing to dampen the ability and interest of inventors to develop new and innovative technologies, compulsory licensing must be carefully considered and narrowly defined to minimize the deleterious effect on China’s attempts to build an innovative economy. Proper judicial review and clarification of the scope of use and licensing details for compulsory licenses can ensure the measured use of compulsory licensing and can protect against overly broad licenses.

USCBC and its member companies appreciate SIPO’s efforts to provide a better regulatory environment for all enterprises in China, and recognize the complexity of intellectual property laws and regulations. We hope that these comments are constructive in SIPO’s efforts to promote and protect companies’ intellectual property rights. To further improve upon these measures and promote innovation through the protection of intellectual property rights for all enterprises in China, we respectfully recommend the following clarifications, additions, and revisions to certain provisions in the draft measures.

Scope of Usage for Compulsory Licenses

Anti-Monopoly Provisions
USCBC recognizes the need under limited circumstances to issue compulsory licenses, and China’s desire to promote fair competition among enterprises. Article 5 of these draft Measures stipulates that if a
patentee’s use of the patent in question is considered anticompetitive, then an individual or other entity may be granted a compulsory license in order to eliminate the monopoly. Such language echoes Article 31(c) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) stating that compulsory licenses may be issued to remedy practices ruled anticompetitive by a judicial process. However, this draft does not contain clear language specifying the judicial process regarding antimonopoly rulings, nor does it provide additional clarification as to what constitutes “anticompetitiveness.” For reference, TRIPS includes specific language that defines what is meant by the term “anticompetitive,” which provides important clarification for both companies and regulators on how to make compulsory licensing determinations.

We request that the draft be revised to include such language, both to benefit domestic stakeholders and also to bring these regulations in closer accordance with TRIPS. USCBC therefore respectfully recommends that the sentence be rewritten as follows: “If a patentee’s exercise of the patent right is determined in a final, non-appealable judgment to be anti-competitive under the PRC Anti-Monopoly Law by a judicial authority or an anti-monopoly enforcement authority and the grant of a compulsory license is the only effective remedy for the patentee’s conduct, SIPO shall issue a compulsory license to correct this conduct and clearly define the scope of use for the compulsory license.” This language would clarify and streamline the process of determining anti-competitive behavior, saving the valuable resources of SIPO and private entities. This would also prevent the underlying compulsory license from taking effect prior to a final and non-appealable judicial or administrative decision.

Additionally, given the authority invested in China’s new Antimonopoly Law, we recommend that Article 11, paragraph 2, be rewritten to include “violates the PRC Anti-Monopoly Law” to clarify the guidelines and requirements by which a patent has been used to establish a monopoly.

**Non-Commercial Public Use**
USCBC and its members recognize the reasons behind including specific language in Article 6 of these regulations to grant compulsory licenses “in cases of national emergency or any extraordinary state affairs, or for the purpose of public interest.” In such cases where compulsory licensing is necessary to deal with national emergency or public interest, we suggest that such compulsory licenses should be issued for specific, non-commercial circumstances. These revisions will help promote consistent implementation of these provisions over time, and better ensure that compulsory licensing is not used to directly or indirectly provide commercial advantage to any one firm over its competitors.

Thus, USCBC recommends that a new sentence be added to Article 6 to read: “In cases where a compulsory license is granted for the public interest, the scope of such compulsory license shall be limited to non-commercial public use.” Additionally, we suggest revising Article 12(a) to add “which is limited to non-commercial public use” after “public interest.”

**Healthcare and Pharmaceutical Patents**
USCBC commends SIPO for mentioning healthcare and pharmaceutical-related patents, revising and improving on the 2006 Regulations on Compulsory Licensing of Patents Related to Public Health. We appreciate new language in Article 22 in the draft measures specifying that these types of compulsory licenses can only be used specifically in emergency situations, barring individual profit.

Article 22 also states that imports of pharmaceuticals will be limited to a predetermined amount as previously requested by the importing party; that special labels will be used for pharmaceuticals manufactured under compulsory licenses; and that drugs exported under a compulsory license will be published in a notice on the company’s website or the relevant WTO website. This is a positive revision
of the earlier Regulations, because it imposes limitations on the use of the compulsory license, and publicizes the use of the license. This change is a positive step forward to ensuring that pharmaceutical and healthcare compulsory licenses will be used solely for non-commercial public purposes.

**Processes and Standards for Granting Compulsory Licensing**

USCBC and its members appreciate that these draft measures seek to provide greater clarity about the process by which compulsory license requests should be made, considered, and determined. To further streamline the process—and to ensure that regulators and companies fully understand the process thereby maximizing limited government resources and minimizing the time and cost burden for companies, we respectively make the following suggestions:

*Extension of Hearing Notice*

Preparing arguments in cases regarding compulsory licensing of patents often requires extensive and thorough preparation by all parties involved. It is therefore necessary to provide sufficient preparation time for both parties, thus ensuring they are fairly and fully represented at the date of the hearing. Article 18, paragraph 2 currently states that SIPO shall notify involved parties of a requested hearing no later than seven (7) days prior to the date of the hearing. USCBC respectfully asks that SIPO extend this notice to thirty (30) working days to give more time to both parties to prepare and help SIPO adjudicators have full information at their disposal to make effective decisions.

*Patentee Response to Compulsory License Request*

Article 16 outlines the patentee’s responsibility for responding to requests “within a prescribed time period.” The Article does not specify a minimum amount of time that must be provided to the patentee in response to a request. Again, companies and SIPO regulators will benefit from sufficient time to prepare materials and respond. USCBC respectfully requests that an insertion be made in the place of “prescribed time period,” to state that “absent a national emergency, the patentee shall have at least a minimum of thirty (30) days to respond to the request.”

*Moderating Compulsory Licensing Requests*

Article 5 describes criteria that shall constitute exploitation of a given patent for the purposes of compulsory licensing determination, including exploitation of a patent within three years following the date when the patent right is granted; or within four years following the date of application for which the patent is submitted. Article 5, however, does not address the importation of products covered by the patent for which a compulsory license is being requested—an activity that results in patented products being sold in the China market just as much as manufacturing those products in China proper. To fully cover the range of activities that exploit a patent, USCBC encourages SIPO to state that the importation of products covered by the patent in question shall constitute exploitation of the patent, and would be sufficient grounds to reject the request for a compulsory license. Such an expansion would also keep this language consistent with Article 27(1) of the TRIPS Agreement that “patent rights [shall be] enjoyable without discrimination as to…whether products are imported or locally produced.”

We therefore respectfully request that Article 5 be amended to add the following clause: “Exploitation constitutes use of the patent, and applies to products that are both imported and manufactured locally.”

*Repeating Compulsory Licensing Requests*

Articles 15 and 33 in the draft Measures set specific time limits to provide any supplementary compulsory license applicants to supplement any missing documents to SIPO upon request. (Article 15 also states that any failure to provide such documents in time shall be viewed as if “no request of a compulsory license
has been raised.”) USCBC asks that SIPO amend Article 15 to clarify this point, respectfully suggest that this phrase be revised to read “waiver of the requesting party’s right,” meaning that the requesting party cannot make a same request again in the future.

Proper and Thorough Judicial Review
USCBC appreciates that Article 21 describes the judicial processes by which compulsory license decisions are reviewed. Such language is an important part of laying out a clear and transparent process for compulsory licensing, ensuring that all stakeholders have a clear understanding of decision-making channels. Existing language still raises a number of questions about the process, however, including questions about whether a compulsory license could be granted before judicial decisions or appeals.

Adding language stating that a compulsory licensing decision shall not go into effect until patent-holders have a full opportunity to use existing Chinese legal and judicial channels would clarify the relationship between administrative and judicial proceedings, and would better ensure that such decisions were made and reviewed after careful deliberation in keeping with the need to strike a balance between interests. The addition of such language would also help to make sure that the granting of compulsory licenses is compliant with TRIPS, since the TRIPS Agreement stipulates that compulsory licenses should only be issued in narrow circumstances.

Therefore, USCBC respectfully recommends that at the end of the last paragraph, SIPO add a new section as follows: “SIPO shall not grant a compulsory license, until the latest of the following: (i) in the event that a lawsuit filed in a timely fashion by the patentee after SIPO’s notice of intent to grant a compulsory license, the date on which a final judgment upholding SIPO’s decision to grant a compulsory license is rendered by the highest judicial authority from which the patentee seeks a ruling; (ii) if the parties independently agree on the exploitation fee, the date the parties jointly file a written notification of such agreement with SIPO; (iii) 31 days after SIPO’s determination of the compulsory license royalties, if a party does not file a lawsuit; or (iv) in the event that a lawsuit is filed in a timely fashion by a party, the date on which a final judgment upholding SIPO’s decision regarding the compulsory license royalties is rendered by the highest judicial authority from which the patentee seeks a ruling.”

Additionally, USCBC recommends that SIPO amend Article 21(e) to specifically state that for any compulsory license other than one issued pursuant to Article 50 of the PRC Patent Law (which allows for a license to be granted for purposes of public health and stipulates that these products be exported to the relevant countries and territories according to agreements in international treaties that China has acceded to), the ruling should state that the license is predominantly for the supply of the Chinese market as required by TRIPS Article 31(f), unless it is issued pursuant to Article 48(2) of the PRC Patent Law, and inclusion of this provision would render the license ineffective as a remedy to the PRC Anti-Monopoly Law violation at issue.

Compulsory Licensing Royalties
USCBC and its members recognize the debate that concerns royalties for patents that are subject to compulsory licensing, and the balance that regulators seek to strike between licensors and licensees. Fair compensation for patent-holders, however, should remain an important consideration, as it is a decisive factor for inventors as they consider innovating and developing new technology in China. Many stakeholders are concerned that the push for zero or excessively low royalty rates will not compensate them fairly for the use of their patent(s).

Article 24 provides little guidance on what evidence is required to determine the royalties and remuneration for compulsory licensing, and no further guidance comes from other related laws and regulations such as the PRC Antimonopoly Law, PRC Patent Law, or their respective implementing
regulations. Adding this language would give all stakeholders—both licensors and licensees—more information about what to expect in compulsory licensing situations and ensure a smoother licensing process.

Therefore, USCBC requests that new language be added to the end of Article 24(e): “…including evidence as to what the exploitation fee should be. In the event that patent(s) at issue has(have) been previously licensed, the exploitation fee shall be no less than what similarly situated Chinese licensees have agreed to pay for similar patent license rights. If there are no Chinese licensees, then the fee shall be no less than what other licensees outside of China have agreed to pay for the same patent(s). If there are no licensees, then the fee should be no less than a reasonable royalty, based upon objective economic analysis.”

To promote further information and transparency through this process, and to provide additional guidance to stakeholders about how royalty rates are being determined when SIPO grants compulsory licenses, we also request that SIPO amend:

- Article 26 to state: “To determine the amount of the royalty and to ensure that patentee and the requesting party are represented, a hearing shall be set regarding remuneration for the use of the compulsory license.”
- Article 29 to add the amount of the royalty and the legal basis for its determination as part of its published decision. Publishing the basis for determining the royalty rate will help to better explain existing decisions and provide clearer evidence for officials to consider in the event of a judicial review.

**Conclusion**

USCBC thanks SIPO for providing this opportunity to comment on these draft measures. We hope that these comments are constructive and useful to SIPO as it reviews the draft measures, and welcome any further discussion that SIPO may wish to provide on these comments.

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