THE US-CHINA BUSINESS COUNCIL
美 中 贸 易 全 国 委 员 会

US-China Business Council Comments on the Patent Law Amendment (Second Review Draft)

August 16, 2020

On behalf of the more than 220 members of the US-China Business Council (USCBC), we appreciate the opportunity to submit comments on the second draft amendment of the Patent Law of the People's Republic of China (hereby referred to as "the Draft") to the National People's Congress (NPC). We appreciate NPC's continuous efforts in optimizing the legal protection of patent rights and the interests of patent owners. USCBC member companies include leading companies in a variety of fields such as manufacturing, pharmaceuticals, information technology, and services, all of which support China's commitment to enhancing intellectual property (IP) protection, fostering a fair and transparent market environment, promoting innovation and competition, and allocating resources efficiently. They are key stakeholders in China's innovation ecosystem in their roles as inventors, consumers, and investors in research and development (R&D).

USCBC notes that the Draft contains some robust, positive steps to reflect long-lasting concerns raised by our members. We appreciate NPC's revisions on extending patent terms, increasing the maximum cap for willful patent infringement punishment to RMB 5,000,000, and shifting the burden of proof to the infringing party in litigation proceedings. These revisions not only address some of the common obstacles that individual inventors or entities may encounter in practice, but also reflect China's implementation of the commitments put forward in the IP Chapter of the Phase One trade agreement with the United States.

In addition to the positive changes mentioned above, we are pleased to see that Article 75 lays out a prototype for a patent linkage system for pharmaceutical IP in China. The adoption of patent linkage would enable China to simultaneously protect the interests of innovators, safeguard public health, and provide Chinese patients with the access to the most advanced pharmaceutical products in the world. Therefore, we believe that the patent linkage system should not be limited to chemical drugs, but rather should include biologics as well. With regards to the process for generic drug producers applying for marketing approval, the current time frame appears to be unreasonably tight for both patentees and the responsible government bodies. Under the current framework, it would be challenging for patentees to be informed about such applications and respond within 30 days. It would also be challenging for the court or the IP-specialized agency under the State Council to examine and decide validity within 9 months. Additionally, it is unclear how the People's Courts and the State Council will split the responsibilities and executive authorities.

We appreciate this opportunity to express our suggestions and have provided article-specific recommendations in detail below. Companies also expressed concerns about some unrevised articles in the Draft and we have included these comments in an appendix.

Article	Content	Comment	Recommendation
6	"The employer may dispose of its right of filing a patent application for a service invention or its patent right for the service invention according to law to promote the implementation and use of the corresponding invention."	We recommend that where there is an agreement between the employers and inventors, the employers should have the option to rely on said agreement in disposing of their patent rights.	We suggest adding the phrase "or based on an agreement between the entity and the inventor or designer…" This would provide a parallel approach for entities to handle their patents.
15	"The State encourages those employers to whom patent rights have been granted to adopt property right incentives and adopt such means of equities, share options, dividends, etc., such that the benefits of innovation are shared reasonably with the inventors or designers."	While we understand China's aim to encourage invention, it needs to be specified that employers still have the option to choose their own incentive mechanism to inventors in an appropriate manner. We also suggest making it clear that an organization is only responsible for the award or remuneration if the organization is the employer of the inventor or designer, and the organization itself owns a patent right for its employment invention-creation.	We recommend also including "cash bonus" in the language as an option for the employers to reward inventors with one-time lump sum payment, rather than limiting to a share-based award system. Additionally, the final draft should clarify that this clause, while encouraged, is not a mandatory requirement.
20	"The principle of good faith shall be upheld in the application for as well as the exercise of patent rights. The patent right shall not be abused such that the public interest or the legal rights and interests of others is harmed." "The abuse of a patent right that excludes or restricts competition and constitutes monopolistic conduct, shall be dealt with in accordance with the Anti-Monopoly Law of the People's Republic of China."	1) It is commonly understood that "principle of good faith" and "public interests" are typical catch-all concepts. We are concerned that these terms would cause confusion when companies interpret these terms and exercise their patent right.. 2) It is also unclear what legal consequences or administrative measures would apply to failure to uphold good faith, abusing patent	We recommend the implementing regulations elaborate on these terms, providing more clarity, standards, and practical guidance on the meaning of good-faith in regard to patent applications. Such a term should be as precisely and narrowly defined as possible to limit uncertainty to industry. To avoid overinterpretation, we recommend that the lawful enforcement of patents should not constitute monopolistic action.

		rights, and conducting speculation by the Anti-Monopoly Law (AML). 3) The current AML only includes vague language stipulating abuse of intellectual property rights; thus, this article in the Draft would create significant confusion with regards to application of laws.	While we understand the law makers for the AML may be at a different stage of discussing and drafting the AML Revisions and accompanying guidelines, it is critical to provide more clarity on the potentially overlapped clauses contained by AML and the Patent Law. As the abuse of intellectual property rights relevant to the AML is already covered in that law, we suggest deleting this clause from the Patent Law.
25	"For any of the following, no patent right shall be granted: … (5) nuclear transformation methods and substances obtained through nuclear transformation methods."	This draft lacks clarification on what "nuclear transformation method" refers to. In particular, companies are concerned whether this expanded clause intends to prohibit patenting particle acceleration methods for increasing particle energy to realize nuclear transformation, methodologies used to produce an isotope with commercial value, and apparatus/devices used for realizing nuclear transformation. To this end, we are unsure whether the definition for "methods of nuclear transformation" included in Article 4.5 of the Guidelines on Patent Examination issued by the State Intellectual Property Office in 2010 is still applicable.	We suggest the Draft should specify what is meant by "nuclear transformation methods," especially in relation to the items raised in the comments. We also suggest unifying the definition included in previous guidelines, regulations, and other documents issued by the administrative organs.
42	"In order to compensate for the time taken for marketing review and approval of a new drug, the patent administrative	We appreciate the addition of patent term extension for innovative pharmaceuticals. However, the	We recommend accounting for time spent in clinical trials and the time for review of

	department of the State Council may grant a compensation of the patent term for invention patents of new drugs that obtain market approval in China, at the request of the patentee. The compensation period shall not exceed five years, and the total valid patent term shall be no more than fourteen years after launch of the new drug."	extension as proposed only includes time taken for marketing review and approval. Most countries with innovative IP regimes also include time invested in clinical trials, which typically accounts for the most time The definition of new drug here requires additional clarification. It is unclear if patent term extension will apply retroactively to drugs currently on the market	the application when considering the extension of the patent term. We suggest defining a new drug as a drug that is new in that country, as opposed to a drug that has yet to be approved in any other country. Regardless, we suggest clarifying which definition applies here. We suggest clarifying that patent term extension should apply retroactively to drugs currently on the market. To avoid confusion, we recommend making clear that CNIPA will determine the length of patent term extension, with the support of NMPA. Such determination should rely on predictable criteria with minimal discretionary factors.
50	"Where a patentee makes a statement in writing before the patent administrative department of the State Council that it is willing to permit any entity or individual to exploit its patent and the payment method and standard of the license fee are specified, the patent administrative department of the State Council shall announce such open license for the patent. Where an open license statement is filed for a utility model or design patent, a patent evaluation report shall be provided."	While we understand this article regarding open license systems aims to encourage granting an open license, which is also adopted by the United Kingdom and Germany, we believe the patent maintenance fees should be reduced in order to provide economic incentive for the patentee if they meet certain conditions.	We suggest adding a clause to reduce or eliminate patent maintenance fee as an incentive for patentees that are willing to submit an open license statement. By providing direct incentive to patentees, it would further encourage the sharing of valuable intellectual property.

52	"Parties who have disputes arising from the implementation of the open license may request the Patent Administration Department Under the State Council to mediate."	It should be specified that the request for a mediation by the patent administration department must be based on agreement of all involved parties.	We recommend inserting the phrase "upon agreement of both parties" into this clause.
70	"A patent administrative department of the State Council may handle a patent infringement dispute that has a significant impact across the country at the request of a patentee or interested party."	Because patent matters often involve technical and legal complexities, we believe that patent matters are more effectively resolved by the judiciary branch. We believe that it needs a clarification that if a party appeals against an administrative decision, then enforcement of such administrative decision should be suspended while the appeal is pending.	We suggest adding the following clarification into the article: "Administrative decisions shall not be enforceable so long as there is a pending appeal against such a decision."
71	"Compensation for patent infringement shall be determined based on actual losses of the patentee caused by the infringement or profits acquired by the infringer from the infringement. Where it is difficult to determine losses of the right owner or profits acquired by the infringer, compensation may be determined in reference to reasonable multiples of the license fee for that patent. For any intentional infringement of patent rights that falls under serious circumstances, compensation may be determined to be no less than one time or no more than five times the amount determined by the above method." "Where it is difficult to determine either losses of the right owner, profits	1) Actual loss of the right holder, gains of the infringer, and multiple of reasonable royalties are three approaches when calculating statutory damages. We are glad to see that the second draft removed the preferential order between the first two approaches, and we suggest also removing the order of the third approach, thus allowing all three approaches to have equal preference. 2) We are concerned that the term "intentional infringement" may entail an overly broad range of activities as this clause should be designated against those conducts involving	We suggest rephrasing this clause, deleting the language that prioritizes using "the actual losses of the patentee caused by the infringement or profits acquired by the infringer from the infringement" over "reasonable multiples of the license fee for that patent." We recommend changing the term "intentional infringement" to "infringement with malicious, wrongful intentions." Another approach is to provide a detailed definition clarifying the term "intentional infringement." We suggest keeping the minimal statutory damage at RMB 100,000 as included in the first draft of the Patent Law Revision,

	acquired by the infringer, or license fee for the patent, a people's court may, by taking into account such factors as the type of patent, nature and particulars of the infringement, etc., determine compensation to be not exceeding 5 million RMB.	malicious, consciously wrongful behavior done in bad faith. 3) Given the significant cost associated with patent litigation, removing the minimal statutory damage would make patentees less incentivized to protect their patents through litigation. We do appreciate the increased maximum statutory at RMB 5,000,000 that is stipulated by the Draft.	reflecting China's effort to encourage patentees to enforce their patent rights through litigation while justifying the anticipatable cost.
75	"If a patentee or interested party thinks that a relevant technical solution of a drug for which marketing authorization is sought falls within the scope of protection of relevant patent rights recorded on the China Marketed Drugs Patent Information Platform, it may institute an action before a people's court or apply to the patent administrative department of the State Council for an administrative ruling within thirty days from the date the drug supervision and administration department under the State Council publicizes the marketing authorization application for the drug... With respect to a marketing authorization application for a chemical drug that has passed technical review, if the people's court or the patent administrative department of the State Council issues an effective judgment or administrative ruling within nine months from the date	The adoption of patent linkage would enable China to simultaneously protect the interests of innovators, safeguard public health, and provide Chinese patients with the access to the most advanced pharmaceutical products in the world. Therefore, we believe that the patent linkage system should not be limited to chemical drugs, but rather should include biologics. Furthermore, it is not clear as currently written if the term "relevant patents" includes patents for drug substance, drug product, and method of use. With regards to the process for generic drug producers applying for marketing approval, the current time frame appears to be unreasonably tight for both patentees and the	We recommend that the patent linkage system clearly include biologic drugs in addition to chemical drugs. We also recommend that the definition of "relevant patents" explicitly include patents for drug substance, drug product, and the method of use. We suggest providing 90 days for the patentee to take appropriate actions, given the procedural complexities in notarizing and legalizing documents. We also recommend that the current 9-month stay period be extended to align with the real-world time it takes for a first instance judgment to be made, for example, to 24 months. Finally, we look forward to further clarifying documents on the patent linkage system, and hope it delineates clearly the authorities of the People's Courts and the State Council.

	the request from the patentee or interested party is accepted...	responsible government bodies. Under the current framework, it would be challenging for patentees to be informed about such applications and respond within 30 days. It would also be challenging for the court or the IP-specialized agency under the State Council to examine and decide validity within 9 months. The stay period should take at least the same amount of time as it takes to receive a first instance judgement. Additionally, it is unclear how the People's Courts and the State Council will split the responsibilities and executive authorities. Overall, we believe the early patent dispute resolution process lacks details, which include but are not limited to inadequate notice provisions, the cause of action element, and the relationship between invalidity proceedings and infringement proceedings.	

Appendix: Comments on Articles Without Planned Revisions

Article	Content	Comment	Recommendation
22	"Inventiveness means that, compared with the prior art, the invention possesses prominent substantive features and represents notable progress, and the utility model possesses substantive features and represents progress."	Under the current provisions in Article 22, the inventiveness criteria for utility model patents are lower than invention patents. Therefore, a utility model patent is much easier to be granted and is very difficult to be invalidated. It is therefore contradictory then that the patentees of the utility model patent and the invention patent are entitled to the same level of remedy and damage for established infringement.	We recommend making the inventiveness criteria for the utility model patent in line with the criteria for the invention patent. An alternative approach would be to require all utility model applications go through substantial examination. Please see further comments on Article 40 and 41.

24	An invention-creation for which a patent is applied for does not lose its novelty where, within six months before the date of filing, one of the following events occurred: ... (2) where it was first exhibited at an international exhibition sponsored or recognized by the Chinese Government; (3) where it was first made public at a prescribed academic or technological meeting;	1) In practice, it is common that inventors would like to submit a paper based on an invention to a conference or technical journals before a patent application is filed, and such paper submissions may not meet the grace period criteria. Thus the inventors have to hold the paper submission until an application is filed. However, due to the complexity of the patent application process and the patent application documents, which could take months to prepare, this often causes the inventors to miss the opportunity to submit and publish their latest research results in important journals or international conferences. Also, the language describing which international exhibitions are eligible for the grace period is unclear, which could lead to significant confusions. 2) It is not very common for the state government to set a short grace period on the disclosure of invention. For instance,	According to Article 24 of the existing Patent Law and Article 30 of the Implementation Regulation of the Patent Law, it is regulated that the grace period for novelty of 6 months only applies to very limited circumstances. We recommend to: 1) Provide more clarifications on what circumstances would meet the eligibility requirements for the grace period. For instance, which level of government authority can recognize an eligible international exhibition. 2) Extend the grace period in China by at least allowing for publication in journals or internationally recognized conferences without losing novelty.

		the grace period in Japan was set for 12 months in 2018. It would create issues if patents registered abroad cannot be registered in China due to non-compliance with China’s grace period provisions. Such a short grace period would undermine China's patent system and be harmful to business and research in China in comparison to other countries.	

40 & 41	"If no reason for rejection is discerned after an invention patent application is substantively examined, the patent administration department under the State Council shall make a decision on granting of the invention patent right, issue an invention patent certificate, and meanwhile register and announce the same. The invention patent right shall become effective as of the date of announcement."	As discussed above for Article 22, improving the quality of utility model patents would increase the stability of patent rights while minimizing the risk of invalidation when owners of utility model patents seek to enforce their rights. In the meantime, this would avoid the damage to alleged infringers and the waste of judicial resources caused by litigation initiated based on patents that should not have been granted in the first place.	To build on our recommendations from Article 22, we also recommend that passing substantial examination be part of the mandatory requirements for utility model patent application, which would allow for higher quality of granted utility model patents. Alternatively, utility model applicants could be allowed to decide whether or not to go through a substantial examination. The judicial and administrative organs within the government could then provide special treatment to those patents that have gone through substantial examination.

49	Where a national emergency or any extraordinary occurs, or public interests so require, the patent administration department under the State Council may grant a compulsory license for exploitation of an invention patent or utility model patent.	According to the TRIPs Agreement, government authorities may "allow for other use of the subject matter of a patent without the authorization of the rights holder" when there is "a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use".	We believe it is important to keep the wording in the Patent Law consistent with the international agreements that China has committed to. Therefore, we recommend that the circumstances mentioned in Article 49 be described as "non commercial use for public interest."