THE US-CHINA BUSINESS COUNCIL
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US-China Business Council Comments on the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (Draft for Comments)

October 23, 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 draft Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (hereby referred to as "the Measures").

As part of the US-China Phase One trade deal and subsequent IP Action Plan, China committed to establishing a pharmaceutical patent linkage regime by October 2020. A properly implemented patent linkage regime will bring benefits to all pharmaceutical manufacturers in China, both generic and innovative, foreign and domestic. Such a system will allow China's innovative biopharmaceutical sector to continue to develop into an international leader, while also promoting increased access to affordable medicine for Chinese consumers.

The Measures are a positive step towards establishing a pharmaceutical patent linkage system. We welcome the establishment of a unified platform in the Patent Information Registration Platform of Marketed Drugs in China, which is a crucial component to an effective framework. At the same time, USCBC members have concerns that other provisions in the measures may undercut this positive development. For example, the measures put forward a "9-month stay period," for resolving patent disputes, which is too short to be effective. Instead, the stay period should align with the actual time it takes to receive a judgement; in 2017 China's then-CFDA committed to a 24-month stay period, which would be more appropriate. In addition, the Measures treat biological drugs as a separate product from chemical drugs. We feel that treating biological and chemical drugs equally in the measures will not only support development of China's innovative drug ecosystem but will also ensure full compliance with China's Phase One commitments to include biologics fully into its patent linkage system.

We appreciate this opportunity to express our suggestions to the National Medical Products Administration and have included article-specific recommendations on these items and others in detail below.

Article	Content	Comment	Recommendation
3	[**Platform Management**] The national drug evaluation agency is responsible for establishing and maintaining the Patent Information Registration Platform of Marketed Drugs in China (CPIRPMD). When applying for marketing of a drug, the applicant shall independently register the drug name, related patent number, patent type, patent status, patentee, marketing authorization holder, expiry date of patent protection, correspondence address, contact person, contact information, etc. For patents related to marketed drugs, the holder may supplement relevant patent information. The applicant or the drug marketing authorization holder shall be responsible for the authenticity, accuracy and completeness of the relevant patent information submitted by it.	According to article 2, the medical products administration department under the State Council shall establish China's registration platform of marketed drug patent information. To prevent confusion, the national drug evaluation agency should be responsible for the maintenance of the CPIRPMD only, not its establishment. It is possible that the final approved drug is slightly different from the drug originally applied for, for example the indication may be changed. We recommend that patents are listed after marketing approval is granted.	[**Platform Management**] The national drug evaluation agency is responsible for ~~establishing and~~ maintaining the Patent Information Registration Platform of Marketed Drugs in China (CPIRPMD). The drug marketing license holder ~~When applying for marketing of a drug, the applicant~~ shall independently register the drug name, related patent number, patent type, patent status, patentee, marketing authorization holder, expiry date of patent protection, correspondence address, contact person, contact information, etc. within 60 days after marketing approval. For patents related to marketed drugs, the holder may supplement relevant patent information. The ~~applicant or the~~ drug marketing authorization holder shall be responsible for the authenticity, accuracy and completeness of the relevant patent information submitted by it.
4	**[Information Management]** During the drug evaluation period, if an applicant obtains a patent right, it may register the patent information on the CPIRPMD within 30 days from the date of the announcement	At this point it is not clear what kind of supporting documents will need to be submitted. We recommend specifying here what those documents will be.	**[Information Management]** After marketing approval ~~During the drug evaluation period~~, if ~~an applicant~~ the license holder obtains a patent right, it may register the patent information on the CPIRPMD within ~~30~~ 60 days from the date of the

	of the patent grant, and submit the patent information to the national drug evaluation agency. When the registered drug patent information is changed, the applicant or the drug marketing authorization holder shall register the change in the CPIRPMD within 30 days after the change takes effect.	In addition, time needed for notarization and other preparation measures should be considered. Thus we recommend extending the timeline from 30 to 60 days	announcement of the patent grant, and submit the patent information to the national drug evaluation agency. When the registered drug patent information is changed, the applicant or the drug marketing authorization holder shall register the change in the CPIRPMD within ~~30~~ 60 days after the change takes effect.
5	**[Type of Patents Registered on the Platform]** When a chemical drug registration applicant submits an application for a drug marketing authorization, it may register patent(s) for active pharmaceutical ingredient compounds, patent(s) for pharmaceutical composition(s) containing active ingredient(s), and patent(s) for medical use on the CPIRPMD.	We recommend clarifying that salt, ester, hydrate, solvate, isomer, polymorph patents will be included. We also recommend clarifying that that combination and formulation patents will be included.	**[Type of Patents Registered on the Platform]** When a chemical drug marketing license holder obtains the marketing approval ~~registration applicant submits an application for a drug marketing authorization~~, it may register patent(s) for active pharmaceutical ingredient compounds, patent(s) for pharmaceutical composition(s) or formulation(s) containing active ingredient(s), or other forms thereof and patent(s) for medical use on the CPIRPMD. Marketing licensed holders may also register patents for salts, esters, hydrates, solvates, isomers, and polymorph.
6	**[Patent Statement]** …Type IV statement: The patents related to the reference drug included on the CPIRPMD shall be declared invalid, or the generic drugs do not fall into the protection scope of the related patents.	We suggest adding a provision that the generic applicant asserting invalidity or non-infringement shall set forth its basis with particularity. Patent holders should be notified of a Type IV application, and the notification	**[Patent Statement]** …Type IV statement: The patents related to the reference drug included on the CPIRPMD shall be declared invalid, or the generic drugs do not fall into the protection scope of the related patents. Such

	Generic drug applications and corresponding statements are publicized to the public on the information platform of the national drug evaluation agency.	should include the information on the basis of the certification (e.g., a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or not infringed).	applications will necessarily include information on the basis of the certification. Generic drug applications and corresponding statements are publicized to the public on the information platform of the national drug evaluation agency. The national drug evaluation agency shall notify the patentee or interested party if a generic drug applicant submits the fourth type of certification.
7	**[Raising Objections]** If a patentee or interested party has any objections to a patent statement and the basis thereof, it may file a lawsuit in a people's court or apply to the patent administrative department of the State Council for an administrative ruling in connection with whether the relevant technical solutions for the drug to be marketed fall within the protection scope of the related patent within 45 days from the date of publication of the drug marketing authorization application by the national drug evaluation agency. If the patentee or interested party files a lawsuit or applies for an administrative ruling within the prescribed time limit, it shall submit a copy of the acceptance notice to the national drug evaluation agency within 10 days from the date of	Per the comment above, it is crucial that the patent statement include the factual and legal basis of the certification — this is necessary for companies to evaluate whether or not to take legal action. Furthermore, we believe more time is needed to give foreign parties sufficient time for notarization and certification procedures. Thus we recommend extending the timeline from 45 to 90 days, and from 10 to 15 days for submitting the copy of the acceptance notice. If the timeline cannot be extended from 45 to 90 days, alternative fixes could be to allow foreign parties to supplement notarized and legalized POA or corporate documents at a later time after	**[Raising Objections]** If a patentee or interested party has any objections to a patent statement and the basis thereof, it may file a lawsuit in a people's court or apply to the patent administrative department of the State Council for an administrative ruling in connection with whether the relevant technical solutions for the drug to be marketed fall within the protection scope of the related patent within ~~45~~ 90 days from the date ~~of publication of the drug marketing authorization application by the national drug evaluation agency.~~ when the patentee or interested party receives the notification from the national drug evaluation agency. If the patentee or interested party files a lawsuit or applies for an administrative ruling within the prescribed time limit, it shall submit a copy of the acceptance notice to the national drug evaluation agency within ~~10~~ 15 days from the date of filing

	filing with or acceptance by the people's court or the patent administrative department of the State Council. …	accepting the case, or to expressly provide a mechanism for court proceedings to be instituted and accepted without the need for such formality requirements for foreign parties.	with or acceptance by the people's court or the patent administrative department of the State Council. If the patent holder by mistake does not list the relevant drug patent or patent information on the platform, the patent holder/originator shall be given 30 days after it discovers such mistake or the receipt of patent statements notification to make the correction. If the patent originator fails to file the lawsuit or administrative ruling within 90 days after the receipt of written notification, the patent holder or originator shall have the right to file the legal actions against the patent infringement behaviors based on the China Patent Law for its patent rights listed or not listed in the Platform. …
8	**[Waiting Period]** Starting from the date of filing with or acceptance by the people's court or the patent administration department of the State Council, the drug regulatory department of the State Council shall set a 9-month waiting period for the registration of chemical generic drugs…	We feel strongly that a 9-month waiting period is too short. We suggest 24 months for the waiting period. This is in accordance with previous documents, such as CFDA Circular No.55 from 2017.	**[Waiting Period]** Starting from the date of filing with or acceptance by the people's court or the patent administration department of the State Council, the drug regulatory department of the State Council shall set a ~~9~~ 24 month waiting period for the registration of chemical generic drugs…
9	**[Classification Approval]** … if an application for a chemical generic drug submitted with Type III statement passes the technical review, a decision to approve the	Generic applicants should refrain from all commercial activities related to their product before the expiration of the patent.	**[Classification Approval]** …if an application for a chemical generic drug submitted with Type III statement passes the technical review, a decision to approve the marketing shall be made, and it

	marketing shall be made, and it shall be made clear that the drug shall not be marketed until the expiration of the patent.		shall be made clear that the drug shall not be marketed or promise to sell until the expiration of the patent.
10	**[Classification Approval]** For an application for a chemical generic drug submitted with Type IV statement, if a patentee or interested party files a lawsuit in a people's court or applies to the patent administrative department of the State Council for an administrative ruling in connection with whether the relevant technical solutions for the drug to be marketed fall within the protection scope of the related patent within 45 days from the date of publication of the drug marketing authorization application by the national drug evaluation agency, such patentee or interested party shall submit the judgment or decision to the national drug evaluation agency within 10 days of receiving the judgment or decision …	To ensure fairness, the patentee should receive a notification from the national drug evaluation agency in the case of a Type IV submission. In line with above suggestions, we recommend extending the timeline to 90 days from 45 to allow for notarization and other certification processes.	**[Classification Approval]** For an application for a chemical generic drug submitted with Type IV statement, if a patentee or interested party files a lawsuit in a people's court or applies to the patent administrative department of the State Council for an administrative ruling in connection with whether the relevant technical solutions for the drug to be marketed fall within the protection scope of the related patent within ~~45~~ 90 days from when the patentee or interested party receives the notification from the national drug evaluation agency ~~the date of publication of the drug marketing authorization application by the national drug evaluation agency~~, such patentee or interested party shall submit the judgment or decision to the national drug evaluation agency within ~~10~~ 15 days of receiving the judgment or decision …
11	**[Encouragement Policy]** A market exclusivity period shall be granted to the first chemical generic drug that successfully challenged the drug patent and obtained market	The marketing exclusivity period for the generic applicant should be reviewed in tandem with a regulatory data protection framework. Specifically, a holistic	*We suggest the Measures refrain from a 12-month exclusivity period for generic applicants until it can be considered alongside a holistic regulatory data protection framework.*

	approval. The drug regulatory and administrative department under the State Council shall not approve generic applications of the same drug within 12 months from the date of approval of the drug, and the market exclusive period shall not exceed the patent term of the challenged drug. During the exclusive period of the market, the national drug evaluation institution will not stop the technical review. For the generic applications of chemical drug that has passed technical review, the relevant chemical generic drug application shall be transferred to the administrative examination and approval process 20 working days before the expiration of the market exclusive period.	approach to exercise the patent linkage mechanism and to invoke regulatory data protection in practice should be considered. Additionally, it is inconsistent that the Measures provide a 12-month marketing exclusivity period for the first generic applicant, as this exclusivity periods is even longer than the 9-month stay period for the innovator patentee.	
12	**[Classification Treatment]** Registration applicants for biological products and traditional Chinese medicine shall register and declare relevant patent information in accordance with Articles 2, 3, 4, 6 and 7 of these Measures. Sequence structure patents may be registered for biological products, and traditional Chinese medicine composition patents, traditional Chinese medicine extract patents,	If biological products continue to be separated from chemical products, we recommend adding drug composition and use patents to those patents that may be registered for biological products.	**[Classification Treatment]** Registration applicants for biological products and traditional Chinese medicine shall register and declare relevant patent information in accordance with Articles 2, 3, 4, 6 and 7 of these Measures. Sequence structure, drug composition, and use patents may be registered for biological products, and traditional Chinese medicine composition patents, traditional Chinese medicine extract patents, and medical use

	and medical use patents may be registered for traditional Chinese medicines.		patents may be registered for traditional Chinese medicines.
13	**[Classification Treatment]**	We strongly suggest the implement measures treat chemical and biological products equality, including the notification system, stay period, time limit for filing a lawsuit, etc. China commitments in the US-China Phase One trade deal stated that Patent Linkage would apply equally to biological products. There is no logical or legal reason for distinguishing, and so the distinctions in the current draft make it more confusing and complex than necessary.	*Article 13 should be eliminated and the implementing measures should apply equally to biological and chemical products.*
14	**[Remedies]** … The drug marketing license decision that has been approved in accordance with the law shall not be revoked and its effectiveness will not be affected.	If there has been a final, non-appealable decision that determines infringement has occurred, then the drug marketing license should be revoked.	**[Remedies]**...The drug marketing license decision that has been approved in accordance with the law shall not be revoked and its effectiveness will not be affected unless there has been a final, non-appealable decision that determines infringement has occurred.
15	**[Subject Responsibility]** For applicants and their agents who deliberately submit false certifications and other falsifications, or deliberately	We find it unclear how to assess the phrases “intentionally submit false statements” or “intentionally include other unrelated patents	**[Subject Responsibility]** For applicants and their agents who deliberately submit false certifications and other falsifications, or deliberately incorporate other unrelated patents into the

	incorporate other unrelated patents into the China's registration platform of marketed drug patent information, joint punishments for untrustworthiness shall be implemented in accordance with the law, the applicants are not allowed to apply for the registration of this variety again within one year…	into the CPIRPMD". These should be restricted to actions that are explicitly in bad faith. We also suggest there to be a correction mechanism for listing the wrong patents on the CPIRPMD.	China's registration platform of marketed drug patent information, joint punishments for untrustworthiness shall be implemented in accordance with the law, the applicants are not allowed to apply for the registration of this variety again within one year. If such actions were not deliberate, those applicants will be allowed to correct their listings without punishment.
16	**[Implementation Time]** These Measures shall come into force on the day X X.	We would propose a specific timeline for transition to the new platform. We suggest that for drugs that received marketing approval before the patent linkage system takes effect, there will be a 6-month period for foreign companies to list the patents on the CPIRPMD (without the need for any formality requirements for foreign patentees) after the patent linkage framework is implemented.	**[Implementation Time]** These Measures shall come into force on the day X X. For drugs that receive marketing approval before these Measures come into force, there will be a 6-month period in which foreign and domestic companies can list patents on the CPIRPMD to comply with the new patent linkage framework.