- '216 would expire about six months from the date of the hearing. [Yes, and it took nine months for the case to be accepted by the court. Are patentees encouraged to file their request pre-trial injunction closer to the full-term expiry?]
- There are other drugs with similar therapeutic functions. [This may mean that the chance of granting the pre-trial injunction may be reduced if there are few alternatives to the invention.]

Although it is encouraging that the first pre-trial injunction has been granted in China, this may not be very exciting if this can only provide six months' protection to the patentee, notwithstanding that Astellas had suffered from sales infringement for at least 14 months (which should be longer realistically) before the pre-trial injunction was granted, and took Astellas nine months to have the pre-trial injunction request accepted by the Court for hearing. Having said so, grant of pre-trial injunction is not a common practice around the world.

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More moves forward?

Amendments to China's Patent Law

On 3 July 2020, the Chinese National People's Congress (NPC) published the second deliberation draft of the fourth amendments to the Chinese Patent Law (the fourth amendments). **Toby Mak** outlines the changes with his own commentary, at the same time keeping attorneys aware of how the patent laws may still differ from ones they are more familiar with. There are still some striking contrasts – such as one exclusion from patentability, punitive damages, the short limitation period for proceedings and significant penalties for false marking, as well as potential changes in the pharma field reflecting US law (such as term extension and generic drug clearance). Proposed changes to In design law bring more international harmonisation, although the term is only proposed to be extended to 15 years. This article provides an overview of the changes to these fourth amendments for the last five years. While many of the changes in the second deliberation draft are heading in the right direction, some "timely" proposals appear not to have been well thought through, including:

- Adding "first publication for public interest in state emergency or abnormal situation" as an exclusion of non-prejudicial disclosure.
- Adding a complex US-style patent linkage system for drug approval, particularly in an article directed to exclusions from patent infringement.

On 3 July 2020, the Chinese National People's Congress (NPC) published a further draft, for consultation, of amendments to the Chinese Patent Law. This is effectively the fourth draft (but described as the Second Deliberation Draft) of the fourth amendments to the Chinese Patent Law (the fourth amendments) soliciting public comments by the deadline 16 August 2020.

Drafts of the fourth amendments were first proposed by CNIPA in April and December 2015. These were reported in my articles published in the May 2015 and March 2016 issues of the *CIPA Journal*. The second draft in December 2015 had already proposed many changes from the first draft in April 2015.

The draft fourth amendments then stayed dormant for about three years. In January 2019, the NPC issued a "First Deliberation Draft" of the fourth amendments, and has now issued a further draft (the "Second Deliberation Draft"). This article consolidates the proposals in these two "Deliberation Drafts", with comments on the proposals and changes. For ease of reference we have included key proposals in the earlier drafts even though these have not been changed. [The origin of the proposals is indicated: D1 and D2 refer to the first and second drafts of amendments; DD1 and DD2 to the first and second "deliberation drafts" (i.e. third and fourth drafts of amendments).] (My observations are highlighted.)

Subject (origin)	Proposal
CNIPA ADMIN	
Statistics D1, D2, DD1	• Requiring CNIPA to disseminate patent information in a timely manner.
CNIPA PROCEDURE	
Examination procedure -DD1	• Removing the Chinese Patent Re-examination Board's (PRB's back then, now called the Re-examination and Invalidation Department) power to examine issues at re-examination of rejected application other than those specified in the rejection decision, and at invalidation proceeding against a granted patent. [Concerns were raised that this could empower the PRB to invalidate a patent *ex officio*, which may result in this removal.]
Administration -DD1	• Removed compulsory enforcement of administrative mediation.
Procedural requirements +DD1, DD2	• Specifying the deadline to submit priority documents, specifically 16 months from earliest priority date for invention patent and utility model applications, and three months from Chinese application date for design patent. [The purpose of this may be to parallel other jurisdictions, for example Europe. I welcome this change anyway.]
PATENT ATTORNEYS	
Regulation of patent attorneys -DD1	• Removed new provisions on regulating patent attorneys. [The provisions on regulating patent attorneys may become redundant, and could be dealt with by separate sets of regulations.]
PATENTABILITY	
Excluded subject matter D1, D2, DD1, DD2	• Including methods of nuclear transformation as a non-patentable subject matter. [A method of nuclear transformation is already a non-patentable subject matter according to the current Examination Guidelines. Substances obtained by means of nuclear transformation has always been non-patentable subject matter. Methods of nuclear transformation refer to the process of forming one or more new atomic nucleus through fission or fusion. Substances obtained by means of nuclear transformation mainly refer to various radio isotopes manufactured or produced by accelerators, reactors or other nuclear reaction apparatus. However, it should be noted that **use of those isotopes and the apparatus and devices used thereof are patentable subject matter**.]
Prior art +DD2	• Adding "first publication for public interest in state emergency or abnormal situation" as an exclusion of non-prejudice disclosure (article 24). [This may be being introduced due to the recent Covid-19 pandemic. However, the proposed wording is vague and problematic, including the following: ➢ Does this exclusion require the declaration of a state of emergency? ➢ What is "public interest" and an "abnormal situation"? Defined by whom? As a general rule, the more exclusions, the higher uncertainty to the public on their freedom-to operate (i.e. uncertainty on whether patent rights could be granted for a certain application). Even if this is retained, which I am against, more explanations will be required.]
GOOD FAITH AND ABUSE OF PROCESS	
Good faith and abuse of process D1, D2, DD1	• Introduction of good faith principle, i.e. patent applications shall be filed in good faith, and patent rights shall not be used to jeopardize public interest or restrict competitions.
Abuse +DD2	• While removing abusive use of patent rights that jeopardize public interest or restrict competition from the above good faith principle, to specify that such abusive use that results in monopoly will be handled according to the Chinese Anti-monopoly Law (article 20). [I am against this addition as it is redundant "otherwise why does the Anti-monopoly Law exist?" Further, this could be interpreted restrictively that abusive use of patent rights could only be handled by the Chinese Anti-monopoly Law. Therefore, I suggest removing this.]

TERM EXTENSION	
Term extension +DD1, DD2	• Introducing patent term extension for innovative drugs. [Now we know why this was introduced – because of the US-CN trade agreement. See May [2020] *CIPA* 9. Specifically, the suggest extension is for innovative drugs applying for marketing approval simultaneously in China and abroad. The extension is for a period of not more than five years, and the total patent term of such innovative drugs, after launch, shall not exceed 14 years. I am against this due to the following reasons: a. An incorrect/incomplete definition of innovative drugs could create numerous disputes. For example, would a new drug with combination of two known compounds be considered as an innovative drug? This could result in valuable resources being spent in legal battles, instead of on innovation. The repeated disputes over supplementary protection certificates in Europe are an example. a. There is another option to deal with this without involving patents. More specifically, data exclusivity before the drug approval authority, which is the entity actually creating the issue of the longer approval period. The patent system could be left alone. In my own words, please clean up your own mess. However, because of the US-CN trade agreement, this is a done deal, unless the agreement becomes void (which would not be a surprise).]
+DD2	• In addition to patent term extension for patents of innovative drugs, this adds US-style patent term extension due to unreasonable delay at prosecution (article 42). [As with the patent term extension for innovative drug patent, this is required to be introduced by the US-CN trade agreement 2020. Personally, I am against this, as this requires the public, but not the Patent Office, to pay the price of prolonged patent term due to the delay of the Patent Office. The amendments are not clear about how the term extension would be calculated (which I presume would be specified in either the revised Implementation Rules or the Patent Examination Guidelines in the future). Further, such extension requires the patentee to specifically apply for it. This is different from that in the US, where it is automatically granted by the USPTO.]
LIMITATION PERIOD	
Limitation period +DD1, DD2	• Increasing time limit for suing patent infringement from two years to three years. [While this is encouraging, it is not clear why this is not increased to six years as in other leading IP jurisdictions.]
LICENCE OF RIGHT	
Licence of right D1, D2, DD1, DD2	• Introducing the UK-style "licence as of right" mechanism.
+DD1	• Allowing CNIPA to mediate on licence fee dispute for a "licence as of right".
+DD2	• Adding that even the patent is subject to "licence as of right", the patentee can negotiate on licence fees and grant a licence of different licence fees, but not an non-exclusive or sole licence [sole licence is one that the licensor agrees not to grant any additional licences to any other person, but retains the right to make use of the intellectual property] (article 51). [I welcome this change, which provide higher flexibility to the patentee and the licensee.] • When there are disputes on the terms on the "licence as of right", instead of mediation by CNIPA as the only option, the dispute could be resolved by negotiation, and if this fails, could be settled at a court (article 52). [The message I received is - CNIPA, stay focus on your own business, which is to prosecute patents.]
EMPLOYMENT RIGHTS	
Employee rights DD1, DD2	• Specifying that an employer is entitled to dispose of patent rights arising due to employment, and remuneration to employee inventor could be in the form of equity, option and dividend.
Employment -DD1	• Other than the above (specifying employers is entitled to dispose patent rights arising due to employment, and compensation to employee inventor could be in the form of equity, option and dividend), articles on employee's rights and remuneration had been reverted back to those same as in the current law. [The relevant provisions may be put into a separate set of regulations, which in any event would receive much attention from domestic and foreign companies due to concerns on employee inventor/designer compensation.]

PATENT INFRINGEMENT	
Patent infringement +DD2	• Adding a US-style patent linkage system for drug approval (Article 75). The following is a summary of the proposed article: ➢ The patentee (or licensee) could sue at a court or CNIPA if the patentee believes that "the technical solution of a drug applying for marketing approval falls within the patent protection scope registered at the China's registration "platform of marketed drug patent information". ➢ The patentee could sue within 30 days from the date when the marketing approval of the generic is announced. Otherwise, the generic applicant could request a court or CNIPA to confirm that the drug seeking marketing approval does not fall within the patent protection scope. ➢ If the court/CNIPA hands down a decision within nine months from the date of acceptance of the patentee's request, China's FDA could determine whether marketing approval should be issued according to the court's or CNIPA's decision. ➢ CNIPA's decision could be appealed to a court within **15 days** from the date of receipt of CNIPA's decision. [The court's decision is not mentioned as a court's decision is appealable in the first place.] ➢ China's FDA and CNIPA must devise substantive mechanism to link drug marketing approval with patent dispute resolution, which is to be implemented after approval from the State Council. [First of all, it is not clear why the above patent linkage provisions are included in Article 75, which is an article directed to exclusions from patent infringement. Second, the above appears to be very different from the US system according to my understanding, which is as below: When filing for approval of an abbreviated new drug application (ANDA) – the application for approval or a generic drug – the generic drug manufacturer must certify one of the following four grounds: 1. the drug has not been patented; 2. the relevant has already expired; 3. the generic drug will not go on the market until the expiry of the patent; or 4. the relevant patent is not infringed or is invalid. Subject to fulfilment of other requirement, grounds 1 and 2 would allow the FDA to grant the marketing approval immediately. In case of ground 3, the FDA may grant approval on the expiry of the patent term. The problem is for ground 4, in which the generic applicant must notify the patentee of its filing and state the rationale behind these claims. The patentee then has 45 days after notice from the generic applicant to file an infringement suit. If the patent is determined to be valid and infringed, the generic drug will not be approved until patent term expiration. Therefore, the above CN proposal has the following issues: ➢ Is the above US notifying system to be implemented? If not, how would the patentee know "the technical solution of a drug applying for marketing approval falls within the patent protection scope registered at the China's registration platform of marketed drug patent information"? ➢ Why there are only 30 days but not 45 days for suing? ➢ The generic applicant could request a court/CNIPA to confirm that the drug seeking marketing approval does not fall within the patent protection scope if the patentee did not sue within 30 days. Is this automatic, or do the court/CNIPA have to rule on a case-by-case basis, based on submissions form the generic applicant? ➢ China's FDA *could* determine whether marketing approval is issued according to the court's or CNIPA's decision issued in nine months. Therefore, it could be interpreted that the China's FDA could issue the marketing approval *if* the decision was not issued within nine months. Could this allow generic applicant to obtain marketing approval by tactically delaying the issuance of the court/CNIPA's decision? In light of the above, I suggest only retaining the following in a new article instead of in Article 75 directed to exclusions from patent infringement: "China FDA and CNIPA shall devise a substantive mechanism to link drug marketing approval with patent dispute resolution, which is to be implemented after approval from the State Council."]

INFRINGEMENT	
Infringement -DD1	• Removed the article for contributory infringement. [This may become redundant, as "Interpretations (II)" of the Supreme People's Court on patent infringement disputes cases, which were reported in my article in August-September [2016] *CIPA* 28, have already stipulated the related principles.]
Evaluation report D1, D2, DD1, DD2	• In addition to the patentee, the defendant in a utility model or design patent infringe case can provide a patentability evaluation report to a Chinese court. [While it is disappointing that the amendments still do not allow anyone to obtain the report, it only requires CNIPA to change its internal procedure to allow anyone to obtain the report. This could be useful to, for example, potential licensees.]
Damages D1, D2, DD1, DD2	• Introducing, when determining compensation for patent infringement, that if the accused infringer fails to provide account books and materials or provides fake account books and materials subject to a court's order, the court may determine the compensation amount by referencing to the patentee's claims and evidence. See my article published in the July 2019 issue of the CIPA Journal for real life operation.]
DD1, DD2	• Raising punitive damage for *severe* wilful infringement from more than 1 to maximum 3 times, to more than 1 to maximum 5 times. [The catch is "severe", which may make invoking punitive damage difficult. My take from the visits at the Supreme People's Court and the Beijing IP Court is that this "severe" generally refers to repeated infringement after a court decision.]
+DD2	• Specifying that patent infringement compensation should be determined based on the actual loss suffered by the patentee, or profits obtained by the infringer (Article 71), while determination referring to multiples of licence fee remains the same if the above loss or profit could not be ascertained. [By contrast, the current Law specifies that the above determination is first based on the actual loss suffered by the patentee; if the loss could not be ascertained, then based on the profits obtained by the infringer. I welcome this change, it gives the court greater flexibility in determining compensation.]
D1, D2, DD1	• Raising statutory damages from between RMB 10,000 and RMB 1,000,000, to between RMB 100,000 and RMB 5,000,000 (about £11,000 to £550,000).
+DD2	• Changing statutory damages from between RMB 100,000 and RMB 5,000,000, to a cap of RMB 5,000,000, that is, the lower limit of RMB 100,000 is removed (Article 71). [Note that the US-CN trade agreement requires statutory damages close to the cap should be granted.]
LIMITATION PERIOD	
Limitation period +DD1, DD2	• Increasing time limit for suing patent infringement from two years to three years. [While this is encouraging, it is not clear why this is not increased to six years as in other leading IP jurisdictions.]
MARKING	
Marking D1, D2, DD1, DD2	• Increasing fines for patent false marking to maximum five times of relevant income, or maximum RMB250,000 (about £27,000) for relevant income of RMB 50,000 (£5,500) or below.
DESIGNS	
Designs D1, D2, DD1, DD2	• Allowing domestic priority claim for **design** patent application. i.e. a later filed Chinese design patent application can claim priority from an earlier filed Chinese design patent application.
-DD1	• Removing specific recitation of "partial design" as the definition of design.
+DD2	• Adding "partial design" back to the definition of design (Article 2). [This is very encouraging, although this may merely be a comfort move, as domestic priority would be allowed for design application in the previous first deliberation draft (This requires quite some explanation. Those who are interested please contact me.)]
D1, D2, DD1, DD2	• Extending the maximum term of a Chinese design patent from 10 years to 15 years from the application date. [This is to prepare China for the Hague Convention.]

ENFORCEMENT	
Interim injunction -DD1	• Removing provisions on requirements on handling pre-trial injunction. [These are now covered by the Civil Procedure Law amended in 2017, and relevant Supreme People's Court's stipulation effective since 1 January 2019. See my article on the first pre-trial injunction granted in China on a drug patent published on page 22.
CNIPA enforcement DD1	• Removing many provisions to empower CNIPA to enforce patents, while adding the following stipulations: 1. CNIPA could only handle patent infringement cases with significant nationwide influence; and 2. local intellectual property offices could combine cases involving the same patent, and requests superior department to handle cases involving the same patent and several administrative regions.
-DD1	• Removed CNIPA's power to confiscate or destroy the infringing products as well as the components, tools, moulds, devices, and other means used to produce the infringing products or to carry out infringing methods. [This, and compulsory enforcement of administrative mediation, were heavily criticized in the first and second drafts, and were removed in the first deliberation draft.]
DD1, DD2	• CNIPA can only handle patent infringement cases with significant nationwide influence. [In my view, this is retained to save face for CNIPA, as the authority of CNIPA to handle patent infringement cases diminishes significantly from CNIPA's first and second drafts, and in the NPC's first deliberation draft. My understanding is that the idea of allowing CNIPA to handle patent infringement cases receives much criticisms. However, it is intriguing that CNIPA could handle patent infringement cases with significant nationwide influence at all, as these tend to be complex. I believe the court is a more appropriate authority to handle complex cases, and suggest that CNIPA should be allowed to handle *only* design patent infringement cases.]
CNIPA infringement +DD2	• Allowing CNIPA to take certain actions when handling patent infringement case (Article 69). [Notwithstanding that CNIPA could only handle patent infringement cases with significant nationwide influence (see above), this may be yet another face-saving measures. I maintain that this is a bad idea.]
MORTGAGES	
Mortgages -DD1	• Removed new provisions on patent mortgages. [Patent mortgage may become redundant, and could be dealt with by separate sets of regulations.]
TAKE DOWN	
Take down DD1	• In the first and second drafts, online services providers like Taobao were required to take down links once it receivined proof of infringement from the patentee. In the current third draft, online service providers are required to do so only after receiving a court decision, including mediation affirmed by the court.
+DD2	• Removed the article requiring online services providers like Taobao to take down links after receiving a court decision, including mediation affirmed by the court. [This may be removed to reduce redundancy and lobbying from the major online ecommerce platforms in China. In any event, I welcome this change.]

Observations

Many of the changes in the second deliberation draft are heading in the right direction, in particular:

- reducing redundancy with other laws of regulations, like those on regulating patent attorneys, and
- restricting the power of CNIPA on handling patent infringement cases, although some intriguing provisions remain.

On the other hand, some "timely" proposals in the draft appear not to have been well considered, including the following:

- adding "first publication for public interest in state emergency or abnormal situation" as an exclusion of non-prejudice disclosure; and
- adding US-style patent linkage system for drug approval, particularly in an article directed to exclusions from patent infringement.

The fourth amendments have gone back and forth for almost five years, and there may be one more around of draft in light of the above. Let's wait and see.

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