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China: Patent Law Amendment Brings Sea Change to Pharmaceutical Patent Regime

On 17 October 2020, the top legislature in China passed the Fourth Amendment to the PRC Patent Law ("**Amendment**") which will take effect on 1 June 2021. The Amendment is significant as it introduces patent linkage and patent term extensions for pharmaceutical patents. The Amendment reflects the commitments China made in the U.S.-China Phase 1 trade deal and underscores its continuing efforts to improve the patent system.

Patent linkage scheme

Article 76 of the Amendment establishes the long-anticipated patent linkage scheme in China. It aims to allow early resolution of patent disputes between innovators and generic companies during the drug review and approval process.

Under current law, an innovator can only bring a patent infringement suit against a generic company after the generic launch. The *Bolar* exemption, introduced in the Third Amendment to the Patent Law, has shielded generic companies from being held liable for patent infringement in connection with activities related for regulatory approval.

Article 76 now provides for a new cause of action for the court to determine whether the technical solution recited in a generic's marketing authorisation application falls within the scope of an innovator's patent. Notably, this is not framed as a patent infringement action. It appears that both an innovator and a generic company may request a declaratory determination from the court before the generic launch. Article 76 goes on to state that within a prescribed time period, the National Medical Products Administration (**NMPA**) may decide whether to stay the approval of the generic company's marketing authorisation based on an effective judgment from the court.

Equally significant, Article 76 also contemplates administrative adjudication of the disputes between innovators and generic companies before the generic launch. This means that, in addition to the court, the China National Intellectual Property Administration (**CNIPA**) will be vested with the jurisdiction to preside over drug patent disputes.

Article 76 is broadly worded and requires implementing rules to flesh out the complex interplay of patent law and drug regulations, including:

- the regulatory trigger and time limit for an innovator to bring the new Article 76 cause of action;
- the length and conditions of the regulatory stay; and
- the meaning of "effective judgment" pursuant to Article 76 and the circumstances under which NMPA will proceed with approving a generic product.

Further details expected in implementing rules and judicial interpretation

The Amendment expressly leaves it to CNIPA and NMPA to enact rules to implement the patent linkage system. At the same time, the Chinese Supreme Court recently released the draft judicial interpretation concerning patent linkage ("**Patent Linkage JI**") for public comment.

The draft Judicial Interpretation from the Supreme Court sheds further light on how pharmaceutical patent litigation is likely to be shaped:

- the Beijing IP Court will hear Article 76 actions;
- in addition to patentees, licensees and MAH holders may have standing to bring an Article 76 action;
- the court may grant a preliminary injunction against "*imminent* manufacture, use, offer to sell and sale" of the generic product, provided that a bond is posted; and
- despite the bifurcation of patent infringement and validity in China, the court may decide to address the invalidity defence in an Article 76 proceeding if the patent at issue is "clearly invalid".

The framework laid out by Article 76 is ground breaking as it creates a new breed of patent litigation in China. Its impact on the generic entry and overall competition landscape will likely be driven by the details of implementation and associated incentives under the new regime. The draft Patent Linkage JI is expected to take effect on the same day as the Patent Law Amendment, i.e. 1 June 2021. Implementing rules are also in the making. Needless to say, pharmaceutical companies (both innovators and generics companies) should keep a close eye on these developing areas.

Patent term extensions

Under the Amendment, it will be possible to obtain patent term extensions for pharmaceutical patents.

Specifically, Article 42(3) of the Amendment adopts patent term extension for pharmaceutical patents due to regulatory delays. To compensate the time taken for drug review and approval, CNIPA, upon a patentee's request, may extend the term of an invention patent "related to a new drug". According to Article 42(3), the extension period shall be no more than five years and the total post-marketing patent term of the new drug shall not exceed 14 years.

Moreover, and more generally, Article 42(2) provides for patent term adjustment for invention patents where there is an "unreasonable delay" caused by CNIPA during patent examination. A patentee may apply for an adjustment four years after the filing of its patent application and three years after the request of substantive examination of the application. Article 42(2) makes it clear that delays caused by an applicant will not qualify for patent term adjustment.

Further rulemaking will be required to clarify the meaning of "new drug" and what types of drug patents are eligible for extensions under Article 42(3). Another critical issue is whether patent term extensions will apply retroactively after the Amendment becomes effective. Implementing rules are also expected to detail the calculations for extensions and any limitations thereof.

Conclusion

In addition to the changes concerning the pharmaceutical patent regime noted above, the Amendment allows protection for partial designs, enhances patent damages, and codifies preliminary injunctions under the Patent Law. The full translation of the Amendment is set out in the appendix.

This is the first time the PRC Patent Law has been amended since 2008. In more than a decade's time, China has emerged as a top patent filer worldwide. As both domestic and foreign companies have become increasingly sophisticated in pursuing and enforcing patent rights in China, the Amendment is set to unleash a new level of patent activities, ultimately elevating China's role as one of the most important patent jurisdictions.

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Appendix: English translation of the Amendment to the PRC Patent Law

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Article 2 For the purposes of this Law, inventions shall include inventions, utility models and designs. Inventions shall mean new technical solution proposed for a product, a process or the improvement thereof. Utility models shall mean new technical solutions proposed for the shape and structure of a product, or the combination thereof, which are fit for practical applicability. Designs shall mean, with respect to a product, new designs of the shape, pattern, the combination thereof, or the combination of the colour with shape and pattern, which create an aesthetic feeling and are fit for industrial application.	**Article 2** For the purposes of this Law, inventions shall include inventions, utility models and designs. Inventions shall mean new technical solution proposed for a product, a process or the improvement thereof. Utility models shall mean new technical solutions proposed for the shape and structure of a product, or the combination thereof, which are fit for practical applicability. The fourth paragraph of Article 2 is amended as follows: Designs shall mean, with respect to a product, new designs of **the overall or partial shape**, pattern, the combination thereof, or the combination of the colour with shape and pattern, which create an aesthetic feeling and are fit for industrial application.
Article 6 An invention-creation that is accomplished in the course of performing the duties of an employee, or mainly by using the material and technical conditions of an entity shall be deemed an employment invention-creation. For an employment invention-creation, the entity has the right to apply for a patent. After such application is granted, the entity shall be the patentee. For a non-employment invention-creation, the inventor or designer has the right to apply for a patent. After such application is granted, the said inventor or designer shall be the patentee. For an invention-creation that is accomplished by using the material and technical conditions of an entity, if the entity has concluded a contract with the inventor or designer providing the ownership of the right to apply for the patent or the ownership of the patent right, such provision shall prevail.	**Article 6** An invention-creation that is accomplished in the course of performing the duties of an employee, or mainly by using the material and technical conditions of an entity shall be deemed an employment invention-creation. For an employment invention-creation, the entity has the right to apply for a patent. After such application is granted, the entity shall be the patentee. **The entity may dispose of the patent application right and patent right in relation to its service inventions to promote the practice and application of such inventions, in accordance with the law.** For a non-employment invention-creation, the inventor or designer has the right to apply for a patent. After such application is granted, the said inventor or designer shall be the patentee. For an invention-creation that is accomplished by using the material and technical conditions of an entity, if the entity has concluded a contract with the inventor or designer providing the ownership of the right to apply for the patent or the ownership of the patent right, such agreement shall prevail.
Article 16 The entity that is granted a patent shall reward the inventor or designer of a service invention. After such patent is practiced, the inventor or designer shall be given reasonable remunerations according to the scope of application and the economic benefits arising therefrom.	**Article 15 (originally Article 16)** The entity that is granted a patent shall reward the inventor or designer of a service invention. After such patent is practiced, the inventor or designer shall be given reasonable remunerations according to the scope of application and the economic benefits arising therefrom. **The State encourages an entity that is granted a patent to provide the inventor or designer with incentives in the form of equity interests, options, dividends or other**

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	interests, so that the inventor or designer may reasonably share the benefits arising from innovation.
	Article 20 (newly added) **A patent application shall be prosecuted, and patent right be exercised in good faith. No one may abuse patent rights to harm the public interest or the legitimate rights and interests of others.** **The provisions of the Antimonopoly Law of the People's Republic of China shall apply to any monopolistic activity to eliminate or restrict competition by abusing patent rights.**
Article 21 The patent administration department under the State Council and its Patent Review Board shall, according to the requirements of objectivity, fairness, accuracy and timeliness, handle patent applications and requests in accordance with law. The patent administration department under the State Council shall release patent-related information in a complete, accurate and timely manner, and publish patent gazettes on a regular basis. Before a patent application is published or announced, the staff members of the patent administration department under the State Council and the persons concerned shall be obligated to keep such application confidential.	**Article 22 (originally Article 21)** The patent administration department under the State Council shall, according to the requirements of objectivity, fairness, accuracy and timeliness, handle patent applications and requests in accordance with law. The patent administration department under the State Council **shall redouble its effort in the establishment of the public service system of patent information,** regularly publish patent bulletins, release patent information in a complete, accurate and timely manner, **provide basic data of patent information, publish patent gazettes on a regular basis,** publish patent gazettes on a regular basis, **and promote the dissemination and utilization of patent information.** Before a patent application is published or announced, the staff members of the patent administration department under the State Council and the persons concerned shall be obligated to keep such application confidential.
Article 24 An invention for which a patent is applied will not lose its novelty due to any of the following events which occur within six months prior to the application date: i) it is exhibited for the first time at an international exhibition sponsored or recognized by the Chinese Government; ii) it is published for the first time at a specified academic or technological conference; or iii) its contents are disclosed by others without the consent of the applicant.	**Article 24** An invention for which a patent is applied will not lose its novelty due to any of the following events which occur within six months prior to the application date: i) it is publicly disclosed for the first time for the public interest in the event of a national emergency or exceptional circumstances; ii) it is exhibited for the first time at an international exhibition sponsored or recognized by the Chinese Government; iii) it is published for the first time at a specified academic or technological conference; or iv) its contents are disclosed by others without the consent of the applicant.

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Article 25 Patent rights shall not be granted for any of the following: i) scientific discoveries; ii) rules and methods for intellectual activities; iii) methods for the diagnosis or treatment of diseases; iv) animal or plant varieties; v) substances obtained by means of nuclear transformation; and vi) designs that are mainly used for marking the pattern, color or the combination of the two of prints. The patent right may, in accordance with the provisions of this Law, be granted for the production methods of the products specified in Subparagraph (4) of the preceding paragraph.	**Article 25** Patent rights shall not be granted for any of the following: i) scientific discoveries; ii) rules and methods for intellectual activities; iii) methods for the diagnosis or treatment of diseases; iv) animal or plant varieties; v) **methods of nuclear transformation** and substances obtained by nuclear transformation methods; and vi) designs that are mainly used for marking the pattern, color or the combination of the two of prints. The patent right may, in accordance with the provisions of this Law, be granted for the production methods of the products specified in Subparagraph (4) of the preceding paragraph.
Article 29 If, within twelve months from the date the applicant first files an application for an invention or utility model patent in a foreign country, or within six months from the date the applicant first files an application for a design patent in a foreign country, he files an application for a patent in China for the same subject matter, he may enjoy the right of priority in accordance with the agreements concluded between the said foreign country and China, or in accordance with the international treaties to which both countries have acceded, or on the principle of mutual recognition of the right of priority. If, within twelve months form the date the applicant first files an application for an invention or utility model patent in China, he files an application for a patent with the patent administration department under the State Council for the same subject matter, the applicant may enjoy the right of priority.	**Article 29** If, within twelve months from the date the applicant first files an application for an invention or utility model patent in a foreign country, or within six months from the date the applicant first files an application for a design patent in a foreign country, he files an application for a patent in China for the same subject matter, he may enjoy the right of priority in accordance with the agreements concluded between the said foreign country and China, or in accordance with the international treaties to which both countries have acceded, or on the principle of mutual recognition of the right of priority. If, within twelve months from the date the applicant first files an application for an invention or utility model patent in China, **or within six months from the date on which the applicant first files an application for a design patent in China**, he files an application for a patent with the patent administration department under the State Council for the same subject matter, the applicant may enjoy the right of priority.
Article 30 An applicant who claims the right of priority shall submit a written declaration at the time of application and submit, within three months, a copy of the patent application documents filed for the first time. If the applicant fails to submit such written declaration or fails to submit a copy of the patent application documents within the required period, the applicant shall be deemed to have waived the right of priority.	**Article 30** **An applicant who claims the right of priority in relation to an invention or utility model patent** shall submit a written declaration at the time of application and submit, within **sixteen** months **from the date of filing the first application for a patent for invention or utility model**, a copy of the patent application documents filed for the first time. **An applicant who claims the right of priority in relation to a design patent shall submit a written declaration at the time of application and submit, within 3 months, a**

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	copy of the patent application documents filed for the first time. If the applicant fails to submit such written declaration or fails to submit a copy of the patent application documents within the required period, the applicant shall be deemed to have waived the right of priority.
Article 41 The patent administration department under the State Council shall establish a patent reexamination board. If a patent applicant is dissatisfied with the decision rejecting the application by the patent administration department under the State Council, the applicant may, within three months after receipt of the notice, file a request with the patent reexamination board for review. After review, the patent reexamination board shall make a decision and notify the patent applicant. If the patent applicant is dissatisfied with the review decision of the patent reexamination board, the applicant may bring a suit in the people's court within three months from receipt of the notice.	**Article 41** If a patent applicant is dissatisfied with the decision rejecting the application by the patent administration department under the State Council, the applicant may, within three months after receipt of the notice, file a request with **the patent administration department under the State Council** for review. After review, **the patent administration department under the State Council** shall make a decision and notify the patent applicant. If the patent applicant is dissatisfied with the review decision of the **patent administration department under the State Council**, the applicant may bring a suit in the people's court within three months from receipt of the notice.
Article 42 The term of an invention patent shall be 20 years commencing from the date of application. The term of a utility model or design patent shall be ten years commencing from the date of application.	**Article 42** The term of an invention patent shall be 20 years commencing from the date of application. The term of a utility model patent shall be ten years commencing from the date of application. **The term of a design patent shall be 15 years commencing from the date of application.** **If an invention patent is granted after the expiration of four years from the application date of such patent or the expiration of three years from the date of request for substantive examination, whichever occurs later, the patent administration department under the State Council shall, upon the request of the patentee, extend the term of such patent to compensate for any unreasonable delay in granting such invention patent, except for the unreasonable delay caused by the applicant.** **In respect of an invention patent related to a new drug which has been approved for marketing in China, the patent administration department under the State Council shall, upon the request of the patentee, extend the term of such patent to compensate for the time taken for the evaluation and approval of such new drug. Such compensatory extension shall be no more than five years, and the total effective term of such new drug patent after the issuance of its marketing approval shall not exceed 14 years.**

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Article 45 After the patent administration department under the State Council announces the grant of a patent, if any entity or individual believes that the grant of the said patent does not conform to the relevant provisions of this Law, such entity or individual may request that the patent reexamination board declare the said patent right invalid.	**Article 45** After the patent administration department under the State Council announces the grant of a patent, if any entity or individual believes that the grant of the said patent does not conform to the relevant provisions of this Law, such entity or individual may request that the **patent administration department under the State Council** declare the said patent right invalid.
Article 46 The patent reexamination board shall examine and decide on an invalidation request in a timely manner and notify the person that has filed the request and the patentee. The decision to declare any patent invalid shall be registered with and announced by the patent administration department under the State Council. Anyone that is dissatisfied with the decision of the patent reexamination board to invalidate a patent or affirm the validity of a patent may, bring a suit in the people's court, within three months from receipt of the notice. The people's court shall notify the opposite party to the invalidation procedure to participate in the litigation as a third party.	**Article 46** The **patent administration department under the State Council** shall examine and decide on an invalidation request in a timely manner and notify the person that has filed the request and the patentee. The decision to declare any patent invalid shall be registered with and announced by the patent administration department under the State Council. Anyone that is dissatisfied with the decision of the **patent administration department under the State Council** to invalidate a patent or affirm the validity of a patent may, bring a suit in the people's court, within three months from receipt of the notice. The people's court shall notify the opposite party to the invalidation procedure to participate in the litigation as a third party.
Chapter 6 Mandatory License for exploitation of a patent	**Chapter 6 Special License for Practice of a Patent**
	Article 48 (newly added) **The patent administration department under the State Council and the departments for patent affairs under the local people's governments shall, together with the relevant departments at the same level, take measures to strengthen the public service for patents and promote the implementation and application of patents.**
	Article 50 (newly added) **Where the patentee has made a written declaration to the patent administration department under the State Council that it is willing to grant a license to any entity or individual to practice its patent, and has specified the payment terms and rate of royalties, the patent administration department under the State Council shall make a public announcement and issue an open license. Where an open license declaration is made for a utility model or design patent, a patentability evaluation report shall be provided.**

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	Article 51 (newly added) **Any entity or individual wishing to practice a patent for which an open license is available will obtain a license to practice such patent once it notifies the patentee in writing and pays the royalties in accordance with the payment terms and rate of royalties as announced.** **During the period of open license, the annual patent maintenance fee payable by the patentee will be reduced or exempted as appropriate.** **The patentee offering its patent for open license may grant a non-exclusive license after negotiating with the licensee on royalties, but it may not grant any exclusive or sole license of such patent.**
	Article 52 (newly added) **Any dispute arising from the implementation of an open license shall be resolved through negotiations by the parties to such open license. If the parties are unwilling or unable to resolve such dispute through negotiations, they may request mediation by the patent administration department under the State Council or submit such dispute to the competent people's court.**
Article 61 Where any patent infringement dispute relates to an invention patent for a manufacturing process of a new product, the entity or individual manufacturing the identical product shall furnish proof to show that the process used to manufacture its product is different from the patented process. Where any patent infringement dispute relates to a utility model or design patent, the people's court or the administration authority for patent affairs may require the patentee or an interested party to furnish a patentability evaluation report issued by the patent administration department under the State Council after conducting search, analysis and appraisal of the relevant utility model or design, and such report will be used as evidence for trial and handling of the patent infringement dispute.	**Article 66 (originally Article 61)** Where any patent infringement dispute relates to an invention patent for a manufacturing process of a new product, the entity or individual manufacturing the identical product shall furnish proof to show that the process used to manufacture its product is different from the patented process. Where any patent infringement dispute relates to a utility model or design patent, the people's court or the administration authority for patent affairs may require the patentee or an interested party to furnish a patentability evaluation report issued by the patent administration department under the State Council after conducting search, analysis and appraisal of the relevant utility model or design, and such report will be used as evidence for trial and handling of the patent infringement dispute. **The patentee, an interested party or the accused infringer may voluntarily submit such patentability evaluation report.**
Article 63 Where any person passes off a patent, such person shall, in addition to the civil liability under the law, be ordered by the administration authority for patent affairs to correct such act, and such order shall be announced, and the illegal earnings received such person shall be confiscated. Such person may	**Article 68 (originally Article 63)** Where any person passes off a patent, such person shall, in addition to the civil liability under the law, be ordered by the **patent enforcement authority** to correct such act, and such order shall be announced, and the illegal earnings received such person shall be confiscated. Such person may be

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be imposed a fine of no more than four times his illegal earnings or, if there are no illegal earnings, a fine of no more than RMB200,000. Where the infringement constitutes a crime, such person will be subject to criminal prosecution.	imposed a fine of no more than **five times** his illegal earnings or, if there are no illegal earnings **or the illegal earnings are no more than RMB50,000**, a fine of no more than **RMB250,000**. Where the infringement constitutes a crime, such person will be subject to criminal prosecution.
Article 64 In investigating and handling the act suspected of passing off a patent, the administration authority for patent affairs may, based on the evidence collected, make inquiries of the relevant persons, investigate into the matters pertinent to the suspected illegal activity; conduct onsite inspection of the place where the relevant persons are suspected of committing the illegal activities; examine and make copy of the contracts, invoices, accounting books and other materials relating to the suspected illegal activity; inspect the products relating to the suspected illegal activity, and may seize or attach the products as proved by evidence to be counterfeits. The relevant persons shall assist and cooperate with the administration authority for patent affairs in exercising the powers as provided in the preceding paragraph, and shall not resist or impede such exercise of powers.	**Article 69 (originally Article 64)** In investigating and handling the act suspected of passing off a patent, the **patent enforcement authority** may, based on the evidence collected, take the following measures: i) making inquiries of the relevant persons, investigating into the matters pertinent to the suspected illegal activity; ii) conducting onsite inspection of the place where the relevant persons are suspected of committing the illegal activities; iii) examining and making copy of the contracts, invoices, accounting books and other materials relating to the suspected illegal activity; iv) inspecting the products relating to the suspected illegal activity; and v) seizing or attaching the products as proved by evidence to be counterfeits. **When handling a patent infringement dispute upon a request of the patentee or an interested party, the administration authority for patent affairs may take the measures listed in Items (1), (2) and (4) above.** The relevant persons shall assist and cooperate with **the patent enforcement authority or** administration authority for patent affairs in exercising the powers as provided in the preceding two paragraphs, and shall not resist or impede such exercise of powers.
	Article 70 (newly added) **The patent administration department under the State Council may, upon the request of the patentee or an interested party, handle any patent infringement dispute that has a significant impact throughout the country.** **When handling a patent infringement dispute upon a request of the patentee or an interested party, the administration department for patent affairs of the local people's government may join the cases involving the infringement of the same patent within its own jurisdiction; any cross-regional infringement of the same patent may be referred to the administration department for patent affairs of the people's government at a higher level.**

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Article 65 The amount of damages payable for patent infringement shall be assessed on the basis of the actual losses suffered by the patentee due to such infringement; where the actual losses are difficult to be determined, it may be assessed on the basis of the profits which the infringer has earned through the infringement. If it is difficult to determine the losses which the patentee has suffered or the profits which the infringer has earned, the amount may be assessed by reference to the appropriate multiple of the amount of royalties paid on such patent. The amount of damages shall also cover the reasonable expenses incurred by the patentee for stopping the infringement. If it is difficult to calculate the losses of the patentee, the profits which the infringer has earned, and the amount of the royalties on that patent, the people's court may, on the basis of such factors as the type of the patent, nature and circumstances of the infringement etc., determine the amount of the damages from RMB10,000 to RMB1,000,000.	**Article 71 (originally Article 65)** The amount of damages payable for patent infringement shall be **assessed on the basis of the actual losses** suffered by the patentee due to such infringement **or the profits which the infringer has earned through the infringement**. If it is difficult to determine the losses which the patentee has suffered or the profits which the infringer has earned, the amount may be assessed by reference to the appropriate multiple of the amount of royalties paid on such patent. **In a serious case of willful patent infringement, the amount of damages may be determined within a range from one time to five times the amount as determined using the method above.** If it is difficult to calculate the losses of the patentee, the profits which the infringer has earned, and the amount of the royalties on that patent, the people's court may, on the basis of such factors as the type of the patent, nature and circumstances of the infringement etc., determine the amount of the damages **from RMB30,000 to RMB5,000,000**. The amount of damages shall also cover the reasonable expenses incurred by the patentee for stopping the infringement. **In order to determine the amount of damages, the people's court may order the infringer to provide the accounting books and materials relating to the infringement where the patentee has exhausted its burden of proof and where the accounting books and materials relating to the infringement are mainly in the possession of the infringer. Where the infringer fails to provide the same or provides false accounting books or materials, the people's court may determine the amount of damages by referencing the claims of the patentee and the evidence provided by the patentee.**
Article 66 Where a patentee or interested party has evidence to prove that someone else is committing or is going to commit an infringement upon the patent right, and its (his) lawful rights and interests will suffer irreparable damage if the said infringement is not stopped in time, it or he may file an application to the people's court for preliminary injunctions to enjoin relevant act prior to initiating a lawsuit. When an applicant files an application, it shall provide a guarantee. If it or he fails to do so, the application shall be rejected.	**Article 72 (originally Article 66)** Where a patentee or interested party has evidence to prove that someone else is committing or is going to **commit an infringement upon the patent right or any other act that causes impediment to the realization of its rights**, and its (his) lawful rights and interests will suffer irreparable damage if the said infringement is not stopped in time, it or he may file an application to the people's court for **preliminary injunctions to seize certain property, or compel or enjoin relevant act** prior to initiating a lawsuit. **(subsequent clauses deleted)**

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The people's court shall make a ruling within 48 hours as of its acceptance of an application. If it is necessary to extend the time limit in a special circumstance, the time limit may be extended for up to 48 hours. If a ruling is made to stop the relevant act, it shall be executed immediately. If any party refuses to accept the ruling, it (he) may apply for one review. The execution of the ruling is not suspended during the process of review. If the applicant fails to lodge a lawsuit within 15 days after it takes such measures as ordering the stop of the relevant act, the people's court shall lift the said measure. Where there are errors in an application, the applicant shall compensate the party against whom an application is filed for the losses caused by the stop of the relevant act.	
Article 67 To stop a patent infringement, the patentee or an interested party may apply to the people's court for preserving the evidence which is likely to be destroyed or is difficult to obtain in the future. The people's court may order the applicant to provide a guarantee for the preservation. If the applicant fails to do so, its or his application shall be rejected. The people's court shall make a ruling within 48 hours after it accepts an application. If it makes a ruling on preserving the evidence, the ruling shall be executed immediately. If the applicant fails to initiate a lawsuit within 15 days after the people's court has taken the measure of preserving the evidence, the people's court shall terminate the said measure.	**Article 73 (originally Article 67)** To stop a patent infringement, the patentee or an interested party may apply, **in accordance with the law**, to the people's court for preserving the evidence which is likely to be destroyed or is difficult to obtain in the future. **(subsequent clauses deleted)**
Article 68 The statute of limitations on an action against a patent infringement shall be two years commencing from the date on which the patentee or the interested party becomes or ought to become aware of the infringing act. Where anyone uses an invention without paying adequate royalties during the period after the patent application for this invention is published but before the patent is granted, the statute of limitations on the patentee's claim for such royalties shall be two years, commencing from the date on which the patentee becomes or ought to become aware that his invention is used by another person. However, if the patentee becomes or ought to become aware of this fact prior to the grant date of the patent, the counting of the statute of limitations shall commence from the grant date of the patent.	**Article 74 (originally Article 68)** The statute of limitations on an action against a patent infringement shall be two years commencing from the date on which the patentee or the interested party knows or ought to know the infringing act. Where anyone uses an invention without paying adequate royalties during the period after the patent application for this invention is published but before the patent is granted, the statute of limitations on the patentee's claim for such royalties shall be **three years**, commencing from the date on which the patentee **knows or ought to know** that his invention is used by another person. However, if the patentee **knows or ought to know** this fact prior to the grant date of the patent, the counting of the statute of limitations shall commence from the grant date of the patent.

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Article 72 If a person usurps the right to apply for a non-service invention, or usurps any other rights and interests specified in this Law, of an inventor or designer, the violating party shall be subject to administrative sanctions by its employer or the superior competent authority.	**Deleted**
	Article 76 (newly added) **If a dispute arises between an applicant for marketing approval of a drug and the reference drug patentee or an interested party during the process of evaluation and examination of such marketing approval, the relevant party may file a lawsuit with the people's court to seek a judgment on whether the technical solutions used by such drug are covered by the claims of the reference drug patent of others. The medical product administration department under the State Council may decide, within the specified period, whether it will suspend the marketing approval process for such drug, based on the final judgment issued by the people's court.** **The applicant for marketing approval of a drug and the reference drug patentee or an interested party may also seek an administrative ruling from the patent administration department under the State Council in respect of any dispute over the patent related to the drug for which a marketing approval application is filed.** **The medical product administration department under the State Council, together with the patent administration department under the State Council, will formulate the specific measures for linking the drug marketing approval process with the dispute resolution process of relevant patent right during the application process for drug marketing approval. Such measures will be implemented after they are approved by the State Council.**
Article 73 The administration department for patent affairs shall not participate in recommending patented products to the public or any other similar business activities. If the administration department for patent affairs violates the provisions of the preceding paragraph, the authority at the higher level or the supervisory authority shall order it to make a correction and eliminate the bad effects, and confiscate any illegal earnings received by it. If the case is serious, the person directly in charge and other person	**Article 79 (originally Article 73)** The administration department for patent affairs shall not participate in recommending patented products to the public or any other similar business activities. If the administration department for patent affairs violates the provisions of the preceding paragraph, the authority at the higher level or the supervisory authority shall order it to make a correction and eliminate the bad effects, and confiscate any illegal earnings received by it. If the case is serious, the person directly in charge and other person

CURRENT PATENT LAW	AMENDMENT
subject to direct liability shall be imposed administrative sanctions in accordance with the law.	subject to direct liability shall be imposed **sanctions** in accordance with the law.
Article 74 Where the staff members of the authorities for patent administration or other relevant State agencies are derelict in their duties, abuse their power, practice favoritism or commit irregularities and such acts constitute criminal offenses, criminal liabilities shall be imposed. If such acts not yet constitute criminal offenses, administrative sanctions shall be imposed in accordance with the law.	**Article 80 (originally Article 74)** Where the staff members of the authorities for patent administration or other relevant State agencies are derelict in their duties, abuse their power, practice favoritism or commit irregularities and such acts constitute criminal offenses, criminal liabilities shall be imposed. If such acts not yet constitute criminal offenses, **sanctions** shall be imposed in accordance with the law.

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