AIPLA
American Intellectual Property Law Association

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全国人大常委会法制工作委员会
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National People's Congress
Legislative Affairs Commission of the Standing Committee
No. 1 Qianmen West Avenue
Xicheng District
Beijing
People's Republic of China
Zip code: 100805

Re: Comments regarding the 2nd Deliberation Draft of the Amendments to the Chinese Patent Law《专利法修正案草案二次审议稿征求意见》

Dear Sir or Madam,

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to comment on the 2nd deliberation draft of the proposed amendments to the Chinese Patent Law. The comment deadline is August 16, 2020. A chart listing AIPLA's detailed comments is attached. A partial summary of the comments is also provided below.

AIPLA is a national bar association of approximately 8,500 members engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA commends the inclusion in Article 2 of rights in whole or partial designs in design patents and Article 42's extension of design patent term to 15 years. Parts of a product design are independently protectable in many of China's trading partners and under international norms of intellectual property protection, as is the 15-year term. This protection is particularly important for designs that achieve international recognition.

Articles 6 defines who holds rights in service and non-service inventions, encourages fair remuneration and the use of agreements to define or clarify such rights. AIPLA recognizes the improvements in clarity in the present draft over the First Reading but remains concerned that appropriate protection of employer confidential information used in making non-service

inventions be balanced against the inventor's right to file non-service invention patent applications, and in maintaining flexibility in remuneration mechanisms that reflect the realities of modern research and development intensive business entities conducting research internationally.

Article 15 adds requirements that remuneration be provided based on the scope of the application and "economic results," recommending the use of specific profit-sharing mechanisms. AIPLA is concerned that patent valuation is a highly complex endeavor, involving multiple disciplines requiring economists, scientists, engineers, and lawyers to work together to achieve a fair and accurate valuation. Moreover, the factors informing patent value change over time, and based on technical and market considerations. Given these complexities and uncertainties, AIPLA recommends even greater strengthening of the role of employment agreements, inventor agreements, total compensation programs, and like measures, which allow the specifics of inventor contribution to the enterprise to be determined by negotiation between employers and employees.

Article 20 imposes an additional requirement of good faith and seeks to broadly regulate the abuse of patent rights. AIPLA is concerned that such requirements regarding "social ethics" and "public interest" are vague, and recommends that they are redundant relative to other, more functional provisions in law, which are better designed to handle potential abuses. AIPLA recommends that this provision be deleted in favor of other clear, established legal frameworks to avoid confusion or conflict.

Article 24 introduces a new exclusion from what constitutes prior art, in recognition to the nature of collaborative research needs in the face of emergency setting like the present global pandemic. However, AIPLA believes the present amendment to Article 24 misses a clear opportunity to harmonize with more progressive and fair laws on "Grace Periods" generally for pre-filing disclosures of an invention by the inventor, or as derived from the inventor, in a manner that promotes more rapid collaboration within industries, while fairly preserving rights in inventions. AIPLA recommends the clear establishment of a 12-month grace period for disclosures by or derived from the inventor, and that the exclusion specifically apply to considerations of novelty and inventive step.

Article 42, in addition to the extending of the term for design patents mentioned above, also now provides for patent term adjustments and extensions for effective patent term loss due to unreasonable delays in the procurement of patents and unreasonable delays in obtaining regulatory approval for pharmaceuticals. AIPLA commends these steps in harmony with many of its major trading partners, which strongly incentives innovation, particularly in industries which are necessarily impacted by lengthy regulatory paths to the market.

Article 69 extends local administrative enforcement mechanisms established for cases of patent passing off, to administrative cases of infringement. As expressed before, AIPLA respectfully continues to consider the better course would be to provide that patent infringement cases be tried in the civil courts with all the procedural protections afforded in court proceedings. With regard to the proposed amendments to Article 69, AIPLA is concerned that none of the protections of trade secrets and other confidential information, let alone errant seizure of

materials or good, as found in such laws as Article 26 of the Foreign Investment Law are not presently specified.

Article 70 expands the authority for administrative handling of infringement cases, where the concerns expressed for Article 69 likewise apply.

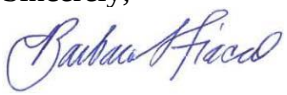
Article 71, AIPLA commends the further development of enhanced damages under certain circumstance, with only reservation regarding clarity concerning what specific accused behaviors would trigger the enhanced damages.

Article 75 includes, for the first time, provisions for a new patent linkage system for the early resolution of patent disputes, prior to the grant of marketing authorization for new generic drug products. AIPLA applauds these provisions and provides comments for clarifying certain critical elements toward enacting a successful patent linkage system.

More detailed comments and proposed amendments are provided in the attached Article by Article comparison and comment table.

We appreciate the opportunity to provide these comments on 2nd deliberation draft of the proposed amendments to the Chinese Patent Law, and we would be happy to answer any questions that our comments may raise.

Sincerely,



Barbara A. Fiacco
President
American Intellectual Property Law Association

Attachment: Table of AIPLA Comments on the 2nd deliberation draft of the proposed amendments to the Chinese Patent Law

Current Patent Law	Patent Law Amendments (Draft) (Second Draft After Reviewing) (2020.06)	AIPLA Comments
Chapter 1: General Provisions	**Chapter 1: General Provisions**	
Article 2. For the purposes of this Law, invention-creations mean inventions, utility models and designs. Inventions mean new technical solutions proposed for a product, a process or the improvement thereof. Utility models mean new technical solutions proposed for the shape and structure of a product, or the combination thereof, which are fit for practical use. Designs mean, with respect to a product, new designs of the shape, pattern, or the combination thereof, or the combination of the color with shape and pattern, which are rich in an aesthetic appeal and are fit for industrial application.	**Article 2.** For the purposes of this Law, invention-creations mean inventions, utility models and designs. Inventions mean new technical solutions proposed for a product, a process or the improvement thereof. Utility models mean new technical solutions proposed for the shape and structure of a product, or the combination thereof, which are fit for practical use. Designs mean, with respect to a product, new designs of the shape in whole or in part, pattern, or the combination thereof, or the combination of the color with shape and pattern, which are rich in an aesthetic appeal and are fit for industrial application.	AIPLA applaud adding "in whole or in part" to the definition of designs to affirm protection of designs-in-part. This represents a significant step toward harmonization of design patent law among major IP jurisdictions.
Article 6. An invention made in carrying out tasks of an entity or made by taking advantage of the material and technical means of the entity is a service invention. The right of patent application of a service invention belongs to the entity. After the patent is granted, the entity is the patentee.	**Article 6.** An invention made in carrying out tasks of an entity or made by taking advantage of the material and technical means of the entity is a service invention. The right of patent application of a service invention belongs to the entity. After the patent is granted, the entity is the patentee. The entity may dispose the right of patent application and the patent right of a service invention in accordance with the law, and promote the implementation and application of the relevant invention.	Article 6 characterizes service inventions as those made (presumably by employees) using "the material and technical means of the entity," understood to be the employer, and provides for the right of the entity (or units) to apply for patents for service inventions, while preserving the right of "the inventor or designer" (presumably an employee) to apply for the patent as a "non-service invention."

For any non-service invention, the right of patent application belongs to the inventor or designer. After the application is approved, the inventor or designer shall be the patentee. For an invention made by taking advantage of the material and technical means of an entity, the right of patent application and the ownership of the patent shall be determined by agreement between the entity and the inventor or designer, if any.	For any non-service invention, the right of patent application belongs to the inventor or designer. After the application is approved, the inventor or designer shall be the patentee. For an invention made by taking advantage of the material and technical means of an entity, the right of patent application and the ownership of the patent shall be determined by agreement between the entity and the inventor or designer, if any.	AIPLA is concerned that this Article may fail to resolve conclusively whether an invention is service or non-service related and may be construed to authorize both the employer and employee to apply for patent protection for the same invention, creating conflicting applications. Further, it may be construed to improperly authorize an employee to file a patent application that discloses to the public information the employer rightfully claims as confidential, is protected as a trade secret, or is protected under the Anti-Unfair Competition Law or other laws governing employee contractual or other duties. AIPLA respectfully suggests the following modification to the language of Article 6: "For any non-service invention, the right of patent application belongs to the inventor or designer, subject to any contract or law, such as the Anti-Unfair Competition Law, that protects the rights of the entity in its confidential information."
Article 14 Where any patent for invention owned by a state-owned enterprise or public institution is of great significance to the interests of the state or to the public interests, the relevant competent department of the State Council and the people's government of the province, autonomous region, or municipality directly under the Central Government may, upon approval of the State Council, decide to popularize and apply the patent within the approved scope, and allow designated entities to exploit the patent; and the exploiting entity		

shall, in accordance with the legal provisions of the state, pay royalties to the patentee.		
Article 16. The unit that is granted the patent right shall reward the inventor or designer of an employment invention-creation. After such patent is exploited, the inventor or designer shall be given a reasonable amount of remuneration according to the scope of application and the economic results.	**Article ~~16~~15.** The unit that is granted the patent right shall reward the inventor or designer of an employment invention-creation. After such patent is exploited, the inventor or designer shall be given a reasonable amount of remuneration according to the scope of application and the economic results. The state encourages the unit that is granted the patent right to implement property rights incentive mechanism and adopt methods including equity, options, and dividends, etc. to enable inventors or designers to reasonably share the proceeds of innovation.	AIPLA notes that the monetary and non-monetary award for employee invention-creation is tied only to patent filing and practice. AIPLA is concerned that such provision may encourage unnecessary or inappropriate patent filings in situations in which patents may not be the optimal protection mechanism. AIPLA further suggests that the law encourage written agreements between an entity and an employee (e.g., signed at the beginning of employment or during the course of employment) to prevail, to reduce or avoid disputes or possible litigation between the employee-inventor/designer and employer as to the ownership of the service invention-creation or appropriate compensation. Article 15 provides for remuneration to the "inventor or designer" of an "employment invention-creation" ("service invention"), and the proposed amendment adds an encouragement to units granted patent rights to implement incentive and remuneration systems for inventors and designers in the units. As with Article 6, AIPLA is concerned about any statutory incentive for an employee to file a patent application intentionally or unintentionally disclosing confidential information learned in employment, perhaps without the invention having being made using "material and technical means" and thus not a "service invention" under Article 6 for which the application is presumably filed by

		the employer. One way of trying to keep work-related inventions within the employing entity is to incentivize disclosure to the employer, such as by the following modification of Article 15: A unit shall reward the inventor or designer of an employment invention-creation for its disclosure to the unit, regardless of whether a patent application is filed or a patent granted. After such invention-creation is exploited, the inventor or designer shall be given a reasonable amount of remuneration according to the scope of application and the economic results. The state encourages the unit that benefits from the invention-creation to implement property rights incentive mechanisms and adopt methods, for example equity, options, and dividends, etc. to enable inventors or designers to reasonably share the proceeds of innovation.
	Article 20. The applying of a patent and exercising of patent rights shall abide by the principle of good faith. Abuse of patents shall not be allowed to harm public interests or others' lawful rights and interests Abuse of patent rights, exclusion or restriction of competition that constituting monopolies shall be dealt with in accordance with the *Anti-monopoly Law of the People's Republic of China*.	AIPLA recommends that the sentence "[t]he application for patent right shall abide by the principle of good faith" be retained and recommends moving it to the beginning of Article 5 where it better fits the context. AIPLA respectfully recommends deleting the rest of Article 20, i.e., the text dealing with "prohibition of misuse of patent rights" for the following reasons: First, this text overlaps, and possibly conflicts with, other relevant existing legislation including: a) Article 55 of Antimonopoly Law. b) Article 329 of the Contract Law c) An SPC Judicial Interpretation that also

		provides that the illegal monopoly technology transfer contract is invalid. d) Article 53(2) of the Patent Law draft provides compulsory licensing as a remedy to eliminate or reduce the negative impact on competition when a patentee's exercise of its patent rights has been deemed as monopoly in accordance with the laws. Second, adding a very general but also vague article in the Patent Law for the prohibition of "misuse of patent rights" would bring no measurable value, and would likely create confusion and potential conflict with the standards found in current specific legislation and judicial interpretation. Third, "harm public interests," is very broad and vague. Construed broadly, it would encompass a wide variety of public interests that would be inconsistent with the affirmed public interest in patent rights incentivizing innovation, as well as international norms of intellectual property protection. The additional reference to the Anti-monopoly Law of the People's Republic of China is redundant, and may be interpreted narrowly to hold that abuse of patent rights constituting a monopoly could only be dealt with by the Anti-monopoly Law, excluding the possibilities of using other existing laws or new laws to legislate violations. This would effectively negate multiple potential alternative techniques for addressing offensive practices under other laws including the Intellectual Property laws.

Article 21. The Patent Administration Department Under the State Council and the Board of Patent Appeals shall, pursuant to the requirements of objectivity, impartiality, accuracy and timeliness, handle the relevant patent applications and appeals. The Patent Administration Department Under the State Council shall completely, accurately and timely announce the patent information and regularly publish patent gazettes. Before an application for patent is published or announced, the functionaries and other relevant persons of the Patent Administration Department Under the State Council shall keep confidential the contents therein.	**Article 21.** The Patent Administration Department Under the State Council and the Board of Patent Appeals shall, pursuant to the requirements of objectivity, impartiality, accuracy and timeliness, handle the relevant patent applications and appeals. ~~The Patent Administration Department Under the State Council shall completely, accurately and timely announce the patent information and regularly publish patent gazettes.~~ The Patent Administration Department Under the State Council shall strengthen the establishment of the public service system of patent information, regularly publish patent gazettes and completely, accurately and timely announce the patent information to provide the basic data of patent information and promote the patent information spreading and utilization. Before an application for patent is published or announced, the functionaries and other relevant persons of the Patent Administration Department Under the State Council shall keep confidential the contents therein.	
Chapter 2: Conditions for Granting Patent Rights	**Chapter 2: Conditions for Granting Patent Rights**	
Article 24. Within six months before the date of application, an invention for which an application is filed for a patent does not lose its novelty under any of the following circumstances: (1) It is exhibited for the first time at an international exhibition sponsored or	**Article 24.** Within six months before the date of application, an invention for which an application is filed for a patent does not lose its novelty under any of the following circumstances: (1) It is publicized for the first time for public interest purposes in time of national emergency or exceptional circumstances;	AIPLA is concerned by the additional exclusion of publication "for the first time for public interest purposes in time of national emergency or exceptional circumstances". International norms of patent protection effectively guarantee pre-publication confidentiality, and this confidentiality is often necessary to provide the rights owner time to develop the invention for commercial

recognized by the Chinese Government; (2) It is published for the first time at a specified academic or technological conference; and (3) Its contents are divulged by others without the consent of the applicant.	(2) It is exhibited for the first time at an international exhibition sponsored or recognized by the Chinese Government; (3) It is published for the first time at a specified academic or technological conference; and (4) Its contents are divulged by others without the consent of the applicant.	use. Current efforts to harmonize international laws seek greater certainty in establishing novelty. More exclusions create greater uncertainty, including uncertainty whether patent rights could be granted for an invention. Even were this provision retained, clarification is required, as the current wording is unclear: • Does this exclusion require the declaration of a state emergency prior to disclosure? • Under what procedures? • What is the standard when a disclosure will be made under this exception? • What constitutes "public interest" and an "abnormal situation"?
Article 25. For any of the following, no patent right shall be granted: (1) scientific discoveries; (2) rules and methods for mental activities; (3) methods for the diagnosis or for the treatment of diseases; (4) animal and plant varieties; (5) substances obtained by means of nuclear transformation; and (6) the design, which is used primarily for the identification of pattern, color or the combination of the two on printed flat works. For processes used in producing products referred to in items (4) of the preceding paragraph, a patent may be	**Article 25.** For any of the following, no patent right shall be granted: (1) scientific discoveries; (2) rules and methods for mental activities; (3) methods for the diagnosis or for the treatment of diseases; (4) animal and plant varieties; (5) ~~substances obtained by means of nuclear transformation; and~~ nuclear transformation methods and substances obtained by means of nuclear transformation; and (6) the design, which is used primarily for the identification of pattern, color or the combination of the two on printed flat works. For processes used in producing products referred to in items (4) of the preceding paragraph, a patent may be granted in accordance with the provisions of this Law.	

granted in accordance with the provisions of this Law.		
Chapter 3 : Application for Patents	**Chapter 3: Application for Patents**	
Article 29. Where, within twelve months from the date on which any applicant first file in a foreign country an application for patenting an invention or utility model, or within six months from the date on which any applicant first file in a foreign country an application for patenting a design, he or it files in China an application for patenting the same, he or it may, in accordance with any agreement concluded between the said foreign country and China, or in accordance with any international treaty to which both countries are a party, or on the basis of the principle of mutual recognition of the right to priority, enjoy the right to priority. Where, within twelve months from the date on which any applicant first filed in China a patent application for an invention or utility model, he or it files with the Patent Administration Department Under the State Council a patent application for the same, he or it may enjoy the priority right.	**Article 29.** Where, within twelve months from the date on which any applicant first file in a foreign country an application for patenting an invention or utility model, or within six months from the date on which any applicant first file in a foreign country an application for patenting a design, he or it files in China an application for patenting the same, he or it may, in accordance with any agreement concluded between the said foreign country and China, or in accordance with any international treaty to which both countries are a party, or on the basis of the principle of mutual recognition of the right to priority, enjoy the right to priority. Where, within twelve months from the date on which any applicant first filed in China a patent application for an invention or utility model, or within six months from the date on which any applicant first filed in China a patent application for an industrial design. he or it files with the Patent Administration Department Under the State Council a patent application for the same, he or it may enjoy the priority right.	
Article 30. Any applicant who claims the priority right shall submit a written declaration when filing the application, and submit, within three months, a copy of the	**Article 30.** Any applicant who claims the priority right of inventions and utility models shall submit a written declaration when filing the application, and submit, within sixteen months from the date on which any applicant first filed a patent application, a	

patent application document which was first filed; if the applicant fails to submit the written declaration or to meet the time limit for submitting the patent application document, the priority right claim shall be deemed as having not been made.	copy of the patent application document which was first filed. Any applicant who claims the priority right of design patent shall submit a written declaration when filing the application, and submit, within three months from the date on which any applicant first filed a patent application, a copy of the patent application document which was first filed.~~, within three months, a copy of the patent application document which was first filed~~; If the applicant fails to submit the written declaration or to meet the time limit for submitting the patent application document, the priority right claim shall be deemed as having not been made.	
Chapter 4： Examination and Approval of Patent Applications	**Chapter 4：Examination and Approval of Patent Applications**	
Article 41. The patent administration department under the State Council shall establish a patent review board. If a patent applicant is dissatisfied with the decision made by the Patent Administration Department under the State Council on rejecting of the application, he may, within three months from the date of receipt of the notification, file a request with the patent review board for review. After review, the Patent Review Board shall make a decision and notify the patent applicant of the same. If the patent applicant is dissatisfied with the review decision made by the patent review board, he may take legal	**Article 41.** ~~The patent administration department under the State Council shall establish a patent review board.~~ If a patent applicant is dissatisfied with the decision made by the ~~Patent Review Board~~ Patent Administration Department under the State Council on rejecting of the application, he may, within three months from the date of receipt of the notification, file a request with the patent review board for review. After review, the ~~Patent Review Board~~ Patent Administration Department under the State Council shall make a decision and notify the patent applicant of the same. If the patent applicant is dissatisfied with the review decision made by the ~~patent review board~~ Patent Administration Department under the State Council, he may take legal action before the people's court within three months from the date of receipt of the notification.	

action before the people's court within three months from the date of receipt of the notification.		
Chapter 5: Duration, Termination and Invalidation of Patent Rights	**Chapter 5: Duration, Termination and Invalidation of Patent Rights**	
Article 42. The duration of invention patent shall be twenty years, the duration of utility model patent or design patent shall be ten years, as of the date of application.	**Article 42.** The duration of invention patent shall be twenty years, the duration of utility model patent ~~or design patent~~ shall be ten years, the duration of design patent shall be fifteen years, as of the date of application. If an invention patent has been granted after four years from the filing date of the invention patent application and three years from the request for substantive examination, the patent owner may request compensation for the unreasonable delay in granting the invention patent, except for the unreasonable delay caused by the applicant. The State Council may make a decision to extend the duration of invention patents of innovative pharmaceuticals which have been approved for marketing in China, to make up the time used for drug approval, and the extension period shall not exceed five years and the net effective duration of such innovative pharmaceuticals which have market launches shall not exceed fourteen years.	AIPLA welcomes these changes, which are in line with the Hague Convention, and international norms of intellectual property protection. AIPLA also welcomes the addition of patent term adjustments and extensions (PTE) for loss of term due to delays in examination, granting a patent, and obtaining pre-marketing authorization for pharmaceutical products, in line with international agreements and norms of patent protection. AIPLA notes that extension of the patent term for unreasonable delay in granting an invention patent is granted only upon request of the patentee. APILA suggests that such compensation be granted automatically by the CNIPA upon granting of the patent, rather than in the discretion of the State Council, as the CNIPA possesses the information necessary to make the adjustment, could efficiently provide all adjustments due, and could publish the adjusted terms on the patent certificate as granted. With regard to the PTE provision, AIPLA has concerns that some of the terms are ambiguous as to whether all patents covering new pharmaceutical products, their methods of manufacture, and approved method of use, and whether discretion is allowed on the part

		of the State Counsel regarding the grant of the term extension. as obligated under the US-China Trade Agreement. Further, there is ambiguity in the phrase 'net effective duration . . . shall not exceed 14 years' in its application to only the extension of the normal patent term. AIPLA suggests amending the language to remove these ambiguities and more clearly align with the Trade Agreement's obligations. And, the loss of effective patent term for a pharmaceutical product includes that time spent in clinical development of the product, obtaining the data package needed to support the regulatory filing. This should be more expressly provided for in the statutory language. An example of an amendment correcting this point would be: *The State Council ~~may~~ shall ~~make a decision to~~ extend the duration of invention patents ~~of innovative pharmaceuticals which have been approved for marketing in China,~~ **covering a new pharmaceutical product approved for marketing in China, its approved method of use, or a method of making the approved product to** make up the time used for drug **clinical development and** approval.~~, and~~ **The length of** the extension period shall not exceed five years and the net effective duration of ~~such innovative pharmaceuticals which have market launches~~ **an extended patent** shall not exceed fourteen years **from the date of marketing authorization**.*

Article 45. Beginning from the date the patent administration department under the State Council announces the grant of a patent right, if a unit or individual believes that such grant does not conform to the relevant provisions of this Law, it or he may request that the patent review board declare the said patent right invalid.	**Article 45.** Beginning from the date the Patent Administration Department under the State Council announces the grant of a patent right, if a unit or individual believes that such grant does not conform to the relevant provisions of this Law, it or he may request that the ~~patent review board~~ Patent Administration Department under the State Council declare the said patent right invalid.	
Article 46. The patent review board shall examine the request for declaring a patent right invalid and make a decision in a timely manner and notify the requesting person and the patentee of its decision. The decision on declaring a patent right invalid shall be registered and announced by the patent administration department under the State Council. A person that is dissatisfied with the patent review board's decision on declaring a patent right invalid or its decision on affirming the patent right may take legal action before a people's court, within three months from the date of receipt of the notification. The people's court shall notify the opposite party in the invalidation procedure to participate in the litigation as a third party.	**Article 46.** The ~~patent review board~~ Patent Administration Department under the State Council shall examine the request for declaring a patent right invalid and make a decision in a timely manner and notify the requesting person and the patentee of its decision. The decision on declaring a patent right invalid shall be registered and announced by the patent administration department under the State Council. A person that is dissatisfied with the ~~patent review board~~ Patent Administration Department under the State Council's decision on declaring a patent right invalid or its decision on affirming the patent right may take legal action before a people's court, within three months from the date of receipt of the notification. The people's court shall notify the opposite party in the invalidation procedure to participate in the litigation as a third party.	

Chapter 6: Compulsory License for the Exploitation of Patent	**Chapter 6: ~~Compulsory License~~ Special License for the Exploitation of Patent**	
	Article 48. The Patent Administration Department Under the State Council and the administrative authority for patent affairs under the local people's government shall, together with the relevant departments at the same level, take measures to strengthen the public service for patent and promote the implementation and application of patent.	
	Article 49. If an invention patent of a state-owned enterprise or public institution is of great significance to the national interest or public interest, the relevant competent department of the State Council and the people's government of a province, autonomous region or municipality directly under the central government may decide to promote the application within the scope of the approval upon approval by the State Council. Designated unit will be allowed to implement and shall make royalty payment to the patentee in accordance with national regulations.	

	Article 50. If the patentee declares in writing to the Patent Administration Department Under the State Council that it is willing to license any party to implement its patent and specify the payment methods and standards of royalties, it shall be announced by the Patent Administration Department Under the State Council and execute "open license". If the patentee declares an open license of utility models or design patents, he or it shall provide patent evaluation reports. In case where such declaration is withdrawn, it shall submit a written withdrawal declaration to the patent administration department for announcement. The validity of such open license before the withdrawal shall not be affected.	AIPLA has several concerns regarding the mechanism described in Articles 50 & 51. First, the text fails to clarify that such declaration of "willing[ness] to license any entity or individual" should be voluntary. Second, the text lacks any mechanism to incentivize users of such declared patents to pay the agreed fee rather than to infringe. We recommend the following revisions: (1) Making the declaration voluntary: "If the patentee declares in writing ***voluntarily*** to the Patent Administration Department Under the State Council." (2) In line with WTO TRIPS Article 41(1) add this sentence at the end of Article 50: "The existence of a declaration under this article shall not derogate from the patentee's right for an effective action against any act of infringement of its patent, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements."

	Article 51. Any entity or person willing to implement the open licensed patent may obtain the open license by sending a written notice to the patentee and paying the standardized license fee according to the announcement. During the open license period, the patentee may also negotiate with the licensee for royalties and grant a general license, but may not grant an exclusive or exclusive license in respect of the patent.	
	Article 52. Parties who have disputes arising from the implementation of the open license may negotiate; if the are unwilling to negotiate or the negotiation fails, they may request the Patent Administration Department Under the State Council to mediate or file the suit in the people's court.	
Chapter 7: Protection of Patent Rights	**Chapter 7: Protection of Patent Rights**	
Article 61. Where any infringement dispute relates to a patent for invention for a process for the manufacture of a new product, any entity or individual manufacturing the identical product shall furnish proof to show that the process used in the manufacture of its or his product is different from the patented process. Where the patent infringement relates to a patent for utility model or design, the people's court or the administrative	**Article ~~61~~66.** Where any infringement dispute relates to a patent for invention for a process for the manufacture of a new product, any entity or individual manufacturing the identical product shall furnish proof to show that the process used in the manufacture of its or his product is different from the patented process. Where the patent infringement relates to a patent for utility model or design, the people's court or the administrative authority for patent affairs may ask the patentee or an interested party to furnish an evaluation report of patent right which is made by the Patent Administration Department	

authority for patent affairs may ask the patentee or an interested party to furnish an evaluation report of patent right which is made by the Patent Administration Department Under the State Council after conducting a search, analysis and evaluation for the related utility model or design, and which is the evidence to judge or handle patent infringement disputes.	Under the State Council after conducting a search, analysis and evaluation for the related utility model or design, and which is the evidence to judge or handle patent infringement disputes. The patentee, interested party or alleged infringer may also issue a patent evaluation report on its own initiative.	
Article 63. Where any person passes off the patent, he shall, in addition to bearing his civil liability according to law, be ordered by the administrative authority for patent affairs to amend his act, and the order shall be announced. His illegal earnings shall be confiscated and, in addition, he may be imposed a fine of not more than four times his illegal earnings and, if there is no illegal earnings, a fine no more than RMB 200,000. Where the infringement constitutes a crime, he shall be prosecuted for his criminal liability.	**Article ~~63~~68.** For patent false marking in addition to bearing his civil liability according to law, be ordered by the ~~administrative authority for patent affairs~~ administrative authority for patent enforcement to correct the act, and the order shall be announced, illegal earnings shall be confiscated and, a fine of not more than ~~four~~ five times of the illegal earnings could be imposed and, if there is no illegal earnings or the illegal earnings are less than RMB 50,000, a fine no more than RMB ~~200,000~~ 250,000. Where the infringement constitutes a crime, criminal liability according to law shall be prosecuted.	
Article 64. When investigating and prosecuting the alleged act of passing off the patent, the administrative authority for patent affairs may, based on the evidence obtained, inquire the parties involved, and investigate the facts relevant to the alleged illegal act; carry out an on-the-spot inspection of the site where the party's alleged illegal act took place; inspect and duplicate the contracts,	**Article ~~64~~69.** The department in charge of patent enforcement shall have the right to take the following measures when investigating and prosecuting suspected counterfeiting patents based on the evidence already obtained: (1) based on the evidence obtained, inquire the parties involved, and investigate the facts relevant to the alleged illegal act; (2) carry out an on-the-spot inspection of the site where the party's alleged illegal act took place;	Article 69 would allow law enforcement agencies, as well as patent administrative agencies, to investigate, inspect, and retain evidence related to patent infringement disputes. AIPLA remains concerned that the proliferation of administrative enforcement mechanisms at multiple levels of the government (country, provincial, and municipal level) may create additional conflicts, prevent the development of clear uniform rules and practices, and create unnecessary risks to commercially sensitive or

invoices, account books and other relevant materials related to the alleged illegal act; and examine the products related to the illegal act and seal up or seize the products that are proved by evidences to pass off a patent. The parties shall assist and cooperate with the administrative authority for patent affairs in exercising the functions and authorities prescribed in the preceding paragraph in accordance with law, and may not refuse or impede them.	(3) inspect and duplicate the contracts, invoices, account books and other relevant materials related to the alleged illegal act; (4) examine the products related to the illegal act, and; (5) seal up or seize the products that are proved by evidences to pass off a patent. When handling patent infringement disputes at the request of patent owners or interested parties, the administrative department of patents may take the measures listed in items (1), (2), and (4) of the preceding paragraph. The parties shall assist and cooperate with the administrative authority for patent affairs and the administrative authority for patent enforcement in exercising the functions and authorities prescribed in the preceding two paragraphs in accordance with law, and may not refuse or impede them.	secret information. Proposed Article 69 does not explicitly include any of the protections of Article 26 of the Foreign Investment Law to restrict access to such information, or provide remedies or an ability to challenge seizure of such information that may include commercial secrets including trade secrets. AIPLA respectfully submits that private enforcement through the courts should be the primary enforcement mechanism and may be better able to serve these goals more efficiently. Therefore, AIPLA suggests removing the provisions on handling patent infringement disputes. Even were these provisions on handling patent infringement disputes retained, AIPLA suggests limiting these provisions to design patents only, as the determination would be simpler and more straightforward than that of invention patent and utility model.
	Article 70. The Patent Administration Department Under the State Council may handle patent infringement disputes that are of nationwide significance in response to the request of the patentee or interested party. The administrative authority for patent affairs under the local people's government may handle patent infringement disputes in response to the requests of patentee or interested parties, and the administrative authority may consolidate those cases that relate to the same patent and relate to the infringement act that occur within its geographic jurisdiction; the cases that involve the infringement of the same patent occurring in cross-jurisdictions may be requested for handling by the authority for patent affairs	Article 70 provides the patent administration department under the State Council discretion to handle any dispute over patent infringement that has a significant impact throughout the country. AIPLA respectfully submits that, consistent with international norms of patent protection and the provisions of TRIPS and WTO, private enforcement should be the primary mechanism for enforcement of patent rights. Thus, China's courts, rather than administrative agencies, may be the better authority empowered to handle patent infringement disputes, absent agreement of all parties. AIPLA is concerned that dividing infringement enforcement authority between the courts and administrative agencies may

	within the upper level people's government .	weaken private enforcement, increase the inconsistency of such determinations, suppress the amount of damages available for infringement, and increase unpredictability, to the ultimate detriment to an innovative society. Therefore, AIPLA suggests removing article 70. Even were Article 70 retained, AIPLA proposes limiting this Article 70 to design patents only, as the determination would be simpler and more straightforward than that of invention patent and utility model.
	(DELETED)	
Article 65. The amount of compensation for the damage caused by the infringement of the patent right shall be assessed on the basis of the losses suffered by the patentee. If it is difficult to determine the losses, the amount 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 suffered by the patentee or the profits earned by the infringer, the amount may be assessed by reference to the appropriate multiple royalties of that patent under contractual license. The amount of compensation shall further include a reasonable expense the patentee has incurred in order to stop the infringing act. The amount of compensation shall further include a reasonable expense the	**Article ~~68~~71.** The amount of compensation for the damage caused by the infringement of the patent right shall be assessed on the basis of the losses suffered by the patentee, ~~If it is difficult to determine the losses, the amount 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 suffered by the patentee or the profits earned by the infringer, the amount may be assessed by reference to the appropriate multiple royalties of that patent under contractual license. ~~The amount of compensation shall further include a reasonable expense the patentee has incurred in order to stop the infringing act.~~ For willful patent infringement with serious circumstances, the amount of compensation shall be determined ranging from one to five times of the amount of compensation determined by the preceding methods. The amount of compensation shall further include a reasonable expense the patentee has incurred in order to stop the infringing act.	AIPLA remains concerned that the revision may be interpreted to mean that an increased damage award for willful infringement is only applicable in "serious circumstances." In other words, to recover increased damages, a patent owner must prove that infringement was both "willful" and the circumstances were serious. This further heightened requirement for "serious circumstances" seems inappropriate and is inconsistent with international norms for awarding enhanced damages. AIPLA suggests alternate language as follows: With respect to willful patent infringement, the damage may be set at an amount between one and three times the amount determined by the aforementioned methods, and further increased to an amount between three and five times in serious circumstances. Additionally, the Article does not provide any guideline on what would be considered as "serious circumstances." This leaves the business community without clear guidance

patentee has incurred in order to stop the infringing act. Where it is difficult to determine the losses suffered by the patentee, the profits which the infringer has earned through the infringement and royalties, the people's court may set an amount of compensation of no less than RMB 10,000 and no more than RMB 1,000,000 in light of factors such as the type of the patent right, the nature of the infringing act and the circumstances.	Where it is difficult to determine the losses suffered by the patentee, the profits which the infringer has earned through the infringement and royalties, the people's court may set an amount of compensation of ~~no less than RMB 10,000 and no more than RMB 1,000,000~~ no more than RMB 5,000,000 in light of factors such as the type of the patent right, the nature of the infringing act and the circumstances. The amount of compensation shall further include the reasonable expense that the patentee has incurred in order to stop the infringing act. In order to determine the amount for compensation, under the circumstances in which the right holder has endeavored to present evidence, and the related account books or materials are mainly in control by the accused infringer, the people's court may order the accused infringer to provide account books and materials relating to the infringing conduct; if the accused infringer does not provide or provides false account books or materials, the people's court may refer to the right holder's claims and evidence to rule on the amount of compensation.	when these provisions would be triggered. China employs a civil law system, as distinct from a common law system. The Amendment, therefore, should provide clear guidance. AIPLA suggests that the Patent Law provide clearer guidance regarding what factors are considered in determining willfulness and when such circumstances are considered "serious." For example, is knowledge of the patent sufficient or are other factors required? By specifying the circumstances in which the people's court may order the infringer to provide the accounting books and materials relating to infringement, and penalties for failure to do so, or for providing false accounting books or materials, the proposed amendments to Article 72 laudably make it easier for the patent infringement claimant to establish the extent of infringing activity for purposes of proving its damages, or to act as the basis for calculating royalties. The proposed language seems appropriate.
Article 66. If the patentee or interested party has evidence to prove that others are conducting or are to conduct any patent infringement, and such act, unless being prevented in a timely manner, will cause irreparable harm to their lawful rights and interests, the patentee or interested party may file an application with the people's court for ordering to have such act ceased before the litigation. When filing such an application, the	**Article 72.** If the patentee or interested party has evidence to prove that others are conducting or are to conduct any patent infringement, and such act, unless being prevented in a timely manner, will cause irreparable harm to their lawful rights and interests, the patentee or interested party may file an application with the people's court in accordance with relevant laws for ordering to have such act ceased before the litigation. ~~When filing such an application, the applicant shall provide guarantee. In the event of failure to provide guarantee, the application may be denied.~~	

applicant shall provide guarantee. In the event of failure to provide guarantee, the application may be denied. The people's court shall make a ruling within 48 hours from receipt of the application. If an extension is needed due to special circumstances, a 48-hour extension may be allowed. If a ruling is made to order to have the relevant act ceased, it shall be enforced immediately. The party dissatisfied with the ruling may apply once for review, and the enforcement shall not be suspended during the period of review. If the applicant fails to file an action within 15 days after the people's court takes the said measures to cease the relevant act, the people's court shall lift such measures. If the application is erroneous, the applicant shall compensate the losses suffered by the respondent for ceasing the relevant act.	~~The people's court shall make a ruling within 48 hours from receipt of the application. If an extension is needed due to special circumstances, a 48-hour extension may be allowed. If a ruling is made to order to have the relevant act ceased, it shall be enforced immediately. The party dissatisfied with the ruling may apply once for review, and the enforcement shall not be suspended during the period of review.~~ ~~If the applicant fails to file an action within 15 days after the people's court takes the said measures to cease the relevant act, the people's court shall lift such measures.~~ ~~If the application is erroneous, the applicant shall compensate the losses suffered by the respondent for ceasing the relevant act.~~	
Article 67. To prevent a patent infringement act, when evidence might be lost or might not be acquired thereafter, the patentee or interested party may file an application with the people's court for evidence preservation. If the people's court takes preservation measures, the applicant may be ordered to provide guarantee. The application	**Article 743.** To prevent a patent infringement act, when evidence might be lost or might not be acquired thereafter, the patentee or interested party may file an application with the people's court for evidence preservation in accordance with the law. ~~If the people's court takes preservation measures, the applicant may be ordered to provide guarantee. The application shall be rejected if the applicant fails to provide the guarantee.~~	

shall be rejected if the applicant fails to provide the guarantee. The people's court shall make a ruling within 48 hours from its acceptance of the application. If it rules to take preservation measures, such a ruling shall be enforced immediately. If the applicant does not file an action within 15 days after the people's court takes preservation measures, the people's court may lift such measures.	~~The people's court shall make a ruling within 48 hours from its acceptance of the application. If it rules to take preservation measures, such a ruling shall be enforced immediately.~~ ~~If the applicant does not file an action within 15 days after the people's court takes preservation measures, the people's court may lift such measures.~~	
Article 68. The period of limitation of action for patent right infringement shall be two years, commencing from the date when the patentee or interested party knows or should know the infringement act. If an appropriate royalty is not paid for using an invention after the invention patent application is publicized and before the patent right is granted, the time limit for action filed by the patentee claiming the payment of royalties shall be two years, commencing from the date when the patentee knows or should know the use of that patent by others. However, the period of limitation of action shall commence from the date when the patent right is granted if the patentee has already known or should know the use before patent right is granted.	**Article 7~~5~~4.** The period of limitation of action for patent right infringement shall be ~~two years~~ three years, commencing from the date when the patentee or interested party knows or should know the infringement act and the infringer. If an appropriate royalty is not paid for using an invention after the invention patent application is publicized and before the patent right is granted, the time limit for action filed by the patentee claiming the payment of royalties shall be ~~two years~~ three years, commencing from the date when the patentee knows or should know the use of that patent by others. However, the period of limitation of action shall commence from the date when the patent right is granted if the patentee has already known or should know the use before patent right is granted.	AIPLA commends the increase of time limitation on bringing a patent infringement lawsuit from two years to three years starting from the date on which the patentee or an interested party knows or should have knowledge of the infringement and the identity of the infringer. This increased time limitation better conforms with international norms. For example, in Germany, claims for patent infringement become unenforceable after three years. In the UK, the limitations period for bringing patent infringement cases is six years. AIPLA notes that further extension of the three-year period may be warranted. In the U.S., legal remedies for infringement are subject to a six-year statutory limitations period and equitable doctrines, including laches, may limit equitable relief where patentee's delay in bringing an action is unjustified. AIPLA also suggests that, in accordance with international norms, this time limitation be interpreted strictly as a bar on an infringement claim, not a time limit on the time-period of

		damage recovery. Finally, AIPLA suggests revising the Chinese wordings "以及侵权人" to "以及侵权人<u>的身份</u>" to enhance readability.
Article 69. The following shall not be deemed to be patent right infringement: (1) After a patented product or a product directly obtained by using the patented method is sold by the patentee or sold by any unit or individual with the permission of the patentee, any other person uses, offers to sell, sells or imports that product; (2) Before the date of patent application, any other person has already manufactured identical products, used identical method or has made necessary preparations for the manufacture or use and continues to manufacture the products or use the method within the original scope; (3) With respect to any foreign means of transportation that temporarily passes through the territory, territorial waters, or territorial airspace of China, the relevant patent is used in the devices and installations for its own needs, in accordance with the agreement concluded between the country it belong to and China, or in accordance with any international treaty to which both	**Article ~~69~~75.** The following shall not be deemed to be patent right infringement: (1) After a patented product or a product directly obtained by using the patented method is sold by the patentee or sold by any unit or individual with the permission of the patentee, any other person uses, offers to sell, sells or imports that product; (2) Before the date of patent application, any other person has already manufactured identical products, used identical method or has made necessary preparations for the manufacture or use and continues to manufacture the products or use the method within the original scope; (3) With respect to any foreign means of transportation that temporarily passes through the territory, territorial waters, or territorial airspace of China, the relevant patent is used in the devices and installations for its own needs, in accordance with the agreement concluded between the country it belong to and China, or in accordance with any international treaty to which both countries have acceded, or on the principle of mutual benefit; (4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation; and (5) For the purpose of providing information required for administrative examination and approval, produces, uses, or imports patented drugs or patented medical apparatus and	AIPLA highly commends the inclusion of the provision for linkage between pharmaceutical marketing approval and the enforcement of patent rights relevant to any reference drug product whose data are used to support the marketing authorization (MA) application for a new drug product (patent linkage hereinafter). AIPLA looks forward to the publication of draft implementing regulations as called for in the article. With regard to the specific provisions proposed, AIPLA has the following comments and suggestions: First, AIPLA suggests the linkage provisions should be placed in a new article, as opposed to the present article concerned with exclusions from patent infringement. Second, AIPLA suggest only retaining "The Drug Administration under the State Council shall work with the patent administration department under the State Council jointly to formulate specific linkage measures for drug market approval and resolution of patent disputes at the stage of market approval applications, and shall implement such measures after being approved by the State Council." This directive should be further detailed to require the regulations to provide at least the elements of an effective linkage

countries have acceded, or on the principle of mutual benefit; (4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation; and (5) Any person produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or produces or any other person imports patented drugs or patented medical apparatus and instruments especially for that person.	instruments, and produces or imports patented drugs or patented medical apparatus and instruments especially for that person. If the patentee or interested party believes that the relevant technical solutions of a drug in market approval application fall within the scope of protection of the relevant patent rights posted on the China Patent Information Registration Platform for Listed Drugs, the patentee or interested party may file a lawsuit with the people's court or apply for an administrative ruling with the patent administrative department of the State Council within 30 days from the date the drug administration department of the State Council announces the application for market approval. If the patentee or interested party fails to file a lawsuit or request for an administrative ruling, the applicant for market approval of the drug may request the People's Court or the patent administrative department under the State Council to confirm that the relevant technical solution of the drug in the market approval application does not fall within the scope of protection of the relevant patent rights listed in China Patent Information Registration Platform for Listed Drugs Where the People's Court or the patent administrative department under the State Council makes an effective decision or administrative ruling within nine months from the date on which the request of the patentee or interested party is accepted, with respect to the application for market approval of the chemical drug that has passed the technical review, the Drug Administration under the State Council may make a decision on market approval, based on the decision of the people's court or the administrative ruling of the patent administrative department under the State Council. If the party concerned is not satisfied with the administrative ruling of the patent administrative department under the State Council, he/she may sue in the people's court within fifteen days from the date of receiving the administrative ruling.	system as discussed below, to assure their proper promulgation. If, however, the current proposed patent linkage provisions are to be retained, AIPLA suggests the following clarifications and amendments: (1) AIPLA suggests that the 30-day period to file suit or request an administrative ruling is too short and will place an undue burden on the patentee or interested party to act hastily at risk of unintentionally missing their opportunity to enforce their patent rights. This is particularly true for foreign parties. AIPLA suggests establishing at least a 60-day period to file an action would better serve the efficient resolution of patent right issues prior to the MA grant without unduly delaying the overall processing time for new drug applications, assuming the intention is to publish notice of new drug applications early in the review process. (2) Same comments are applicable to the 15-day period for filing an appeal to the administrative ruling. AIPLA suggests increasing this period to 30-days. (3) Further, AIPLA presumes that the intended implementing regulations will provide that the announcement of a new MA application will give notice that a particular reference drug's data package is being referenced, and then that adequate (confidential) access to relevant

	The Drug Administration under the State Council shall work with the patent administration department under the State Council jointly to formulate specific linkage measures for drug market approval and resolution of patent disputes at the stage of market approval applications, and shall implement such measures after being approved by the State Council.	information in the announced MA Application dossier will be given to enable the patentee or interested party to determine if the proposed drug would, in fact, infringe the listed patent right prior to their filing suit or requesting an administrative ruling. AIPLA further presumes that procedures will be implemented to otherwise safeguard the confidentiality of the proprietary information of all parties throughout all proceedings and by all agencies and parties. Otherwise, AIPLA suggests clarifying these points in the provision. (4) Although AIPLA feels the proposed announcing (publication) of MA applications referencing data from a previously approved drug (reference drug), with sufficient information, would fulfill notice obligations to the patent holder, licensee or MA Holder, AIPLA suggest that expressly requiring actual notice to the rights holders would be more efficient and easy to implement. (5) AIPLA commends the provision providing the applicant for market approval of the new drug (the generic applicant) the opportunity to request a declaratory ruling to determine whether or not the proposed new drug would infringe the patent if the patentee/ interested party does not file an action within the prescribed time. However, it is not clear if such a declaratory action is to be *inter partes* with full notice and involvement of the patentee/interested

		party. The full participation of the patentee/interested party being a critical component of a fair and efficient linkage system, AIPLA suggests amending this term to clearly specify this. (e.g. inserting, ". . . may request an inter partes proceeding before the Peoples' Court or administrative department . . .") (6) The current draft language suggests that if the People's Court or the patent administrative department did not issue a decision within 9 months of initiation of action, then the Drug Administration could proceed to grant the marketing authorization. under this interpretation, marketing authorizations that should not be granted could proceed to grant by simply by delaying the issuance of the ruling, frustrating the purpose of patent linkage and opening opportunities for inappropriate gamesmanship. As such, AIPLA suggests requiring that the stay from granting a marketing authorization remain in place until a final ruling is provided, where upon it be required NMPA align any decision to grant the marketing authorization with either a decision that the drug product would not infringe the patent, or with a stipulated effective date after the patent's expiration, when the ruling finds the drug product would infringe the patent. An example of an amendment correcting these points and giving strength to the framework shown in the draft provision would be:

		Art 75bis(1) The NMPA shall establish a China Patent Information Registration Platform for Listed Drugs, listing at a minimum, all approved pharmaceutical products (including biologics), their active pharmaceutical ingredient and dosages, approved therapeutic uses, all patents claiming the approved active pharmaceutical ingredient, the approved pharmaceutical product, or an approved therapeutic use, along with their expiration dates, as well as the identity and contact information for the listed marketing authorization holder and all listed patent right holders. Art 75bis(2) Notwithstanding Article 75(5) of this Law, it shall constitute an act of patent infringement to file a marketing application for a pharmaceutical product, including a biologic, under Article [Insert Relevant Article for applications relying at least in part on safety or efficacy data from a prior approved Pharmaceutical Product] of the Drug Registration Regulation that is claimed in a patent listed on the China Patent Information Registration Platform for Listed Drugs. Art. 75bis(3) Upon receiving an application for marketing authorization for a new pharmaceutical product under Article [Insert Relevant Article for applications relying at least in part on safety or efficacy data from a prior approved Pharmaceutical Product] of the Drug Registration Regulation, NMPA will refer to the China Patent Information Registration Platform for Listed Drugs and send notice to

		the reference drug product's listed marketing authorization holder and the listed patent rights holders for all unexpired patents listed with the reference drug product there on, that a new pharmaceutical product application has been filed referencing the reference drug marketing authorization. The NMPA notice will provide relevant bibliographic information for the application and include an invitation to confidentially access the relevant dossier information for the sole purpose of assessing whether the new pharmaceutical product would infringe a listed patent. Art 75bis(4) If a rights holder (the reference drug marketing authorization holder or a listed patent right holder) considers the proposed new pharmaceutical product would infringe one or more listed patent, they may file a lawsuit for infringement with the people's court or apply for an administrative ruling of infringement with the patent administrative department of the State Council (a "Linkage Infringement Action") within 60 days from the date of the NMPA notice of the application. Art 75bis(5) Upon filing a Linkage Infringement Action according to Art 75bis(4), a stay will be issued against NMPA from the final granting of a marketing authorization with regard to the subject application. Further, no stay against the Linkage Infringement Action may be issued with regard to any invalidation action involving a listed patent at issue in the Action.

		Art 75bis(6) If the patentee or interested party fails to file a Linkage Infringement Action within the prescribed period, the applicant for market authorization may request an *inter partes* declaratory action with the People's Court or the patent administrative department under the State Council ("Linkage Declaratory Action") to determine whether or not the proposed new pharmaceutical product would infringe a patent listed with the reference drug marketing authorization. If action is initiated under this 75bis(6), no stay will be issued against the final granting of a marketing authorization with regard to the subject application, and no stay against the Linkage Declaratory Action may be issued with regard to any invalidation action involving a listed patent at issue in the Action. Art 75bis(7) When a final ruling is reached in a Linkage Infringement Action, the stay of the final granting of a marketing authorization shall be lifted. If the final ruling found infringement, NMPA shall make any grant of a marketing authorization regarding the subject application effective only as of the day after the expiry of the patent or patents found to be infringed. When a final ruling of infringement is reached in a Linkage Declaratory Action, NMPA shall make any grant of a marketing authorization regarding the subject application effective only as of the day after the expiry of the patent or patent's found to be infringed and shall suspend any marketing authorization already

		granted until the day after the expiry of the patent or patent's found to be infringed.
Article 72. Where any person usurps the right of an inventor or designer to apply for a patent for a non-service invention, or usurps any other right or interest of an inventor or designer as prescribed in this Law, he shall be subject to an administrative sanction by the entity for which he works or by the competent authority at the higher level.		
Article 73. The administration department for patent-related work shall not be involved in recommending patented products to the public or engage in any other similar business activities. If the administration department for patent-related work violates the provisions of the preceding paragraph, its immediate superior or the supervisory authority shall order it to rectify, and confiscate its unlawful gains, if any; if the circumstances are serious, the principal leading person directly in charge and the other persons directly responsible shall be given administrative sanctions in accordance with law.	**Article 7~~3~~8.** The administration department for patent-related work shall not be involved in recommending patented products to the public or engage in any other similar business activities. If the administration department for patent-related work violates the provisions of the preceding paragraph, its immediate superior or the supervisory authority shall order it to rectify, and confiscate its unlawful gains, if any; if the circumstances are serious, the principal leading person directly in charge and the other persons directly responsible shall be given ~~administrative~~ sanctions in accordance with law.	

Article 74. Where a staff member of the government department engaged in administration of patent-related work or of a relevant department neglects his duty, abuses his power, or commits irregularities for personal gain, which constitutes a crime, he shall be pursued for criminal responsibility in accordance with law. If the case is not serious enough to constitute a crime, he shall be given an administrative sanction in accordance with law.	**Article 749.** Where a staff member of the government department engaged in administration of patent-related work or of a relevant department neglects his duty, abuses his power, or commits irregularities for personal gain, which constitutes a crime, he shall be pursued for criminal responsibility in accordance with law. If the case is not serious enough to constitute a crime, he shall be given an ~~administrative~~ sanction in accordance with law.	