Comment on Draft Amendments to Implementing Regulations of the Patent Law

Company Name: AIPPI JAPAN

The following comments regarding this request for opinion are not representative of AIPPI JAPAN, but are submitted as the opinions of a members of the Association.

Comments	Proposed changes	Reasons
Rule 14 (comment 1)	The revised 2nd paragraph is as follows: *Any license contract for exploitation of a patent which has been concluded by the patentee with an entity or individual shall, ~~within three months from the date of entry into force of the contract~~, be submitted to the patent administration department under the State Council for the record.* ***~~Without this submission, the licensee shall not assert their right against a bona fide third party~~.*** The newly added sentence "Without this submission, the licensee shall not assert their right against a bona fide third party." should be deleted.	For the following reasons, the provision for assertion against third parties based on the submission of license contracts should be deleted: (a) Since many countries do not have a system for registration-based assertion against third parties, foreign companies often do not understand the need to register a contract and it is difficult to get cooperation of them when negotiating an international contract. In the case of a license contract between two non-Chinese companies, in particular, making a registration with the Patent Administration Department under the State Council is costly and time consuming and it is difficult to get understanding and cooperation of a counterparty. (b) There is not a system for registration-based assertion in many countries and it is customary to directly check with a patentee on the existence and details of a non-exclusive license in advance, as part of the due diligence process, when trying to take over a patent. Taking into consideration such international licensing practice mentioned above, a system for registration-based assertion is unnecessary. The addition of a system for registration-based assertion would fail to establish harmony with most other countries where patent license contracts are concluded globally without a system for registration-based assertion. Although China has a system for registration-based assertion for trademarks, this system should not be extended to patent licenses, since compared to trademarks, patents are much more often transferred or licensed based on a contract and therefore registration-based assertion is unsuitable.

		Moreover, the lack of international harmonization in terms of assertion against third parties would be unfavorable to the Chinese industries, where an increase in the number of international license contracts is anticipated.
Rule 14 (comment 2)	*Except for the assignment of the patent right in accordance with Article 10 of the Patent Law, where the patent right is transferred because of any other reason, the person or persons concerned shall, accompanied by relevant certified documents or legal papers, request the patent administration department under the State Council to register the change in the owner of the patent right.* *Where any patent right is pledged, both the pledger and the pledgee shall jointly register the contract of pledge with the patent administration department under the State Council.* The 2nd paragraph "Any license contract ... against a bona fide third party" should be deleted.	The 2nd paragraph should be deleted completely. In the electronics industry, for example, each company has license contracts with many other companies. Most of them are comprehensive contracts under which a large number of patent rights are licensed. To transfer a patent right under these circumstances, the patentee would have to perform an extremely burdensome task to check and inform of which of the license contracts includes that patent right. It is not realistic. Many patent rights are sold or transferred to other parties these days. Under these circumstances, it is likely that a licensee will not be able to assert their right against a third party due to their failure to perform such a burdensome and unrealistic task. It would not be reasonable. In light of the fact that most countries have adopted a system for registration-free assertion, It would be strongly suggested that the provision for submission of license contracts from Rule 14 should be deleted.
Rule 16	*The request of application for patent for invention, utility model or design, shall state the following:* *(1) the title of the invention, utility model or design;* *(2) where the applicant is a Chinese entity or individual, its or his title or name, address, postal code, the ~~code of the organization~~ unified social credit identifier or the citizen identification*	Description of what the "real status information (**真**实身份信息)" in (3) specifically refers to should be provided. The measures to prevent leakage of personal information especially when the applicant is a foreign company should be taken.

	card number; where the applicant is a foreigner, a foreign enterprise or other foreign organization, his or its name or title, the nationality or the country or region in which the applicant is registered; ***(3) the ~~name~~ real status information of the inventor or creator;*** *(4) where the applicant has appointed a patent agency, the name of the appointed agency, the agency's organizational code and the name, the professional certificate number and the telephone number of the patent agent assigned by the agency;* *(5) where the right of priority is claimed, the filing date on which the applicant filed the application the first time (hereinafter referred to as the earlier application), the filing number of the application and the title of the authority with which the application was first filed;* *(6) the signature or seal of the applicant or the patent agency;* *(7) a list of the documents constituting the application;* *(8) a list of the documents appending the application; and* *(9) any other related matters which needs to be indicated.* In item (3) above, the meaning of the "real status information" should be specified.	
Rule 27	The newly added paragraph is as follows:	It is necessary for applicants to understand how to define a part to be protected under the newly created

	"Where a patent for partial design is filed, drawings of the entire product shall be submitted, and the content which is in need of protection shall be illustrated by solid lines in combination with broken lines, or by other ways." The part "other ways" is not clear. The specific descriptions of what "other ways" refer to in the Implementing Regulations or in the Examination Guidelines should be provided. Also, a supplementary explanation of how to define a part to be protected as a partial design using a set of example drawings in the Examination Guidelines should be provided.	partial design system. Therefore, an explanation should be provided in the Implementing Regulations or in the Examination Guidelines. Since it is difficult to adequately understand designs only through written explanation, examples should be given in the Examination Guidelines.
Rule 28	The newly added paragraph is as follows: *"Where a patent for partial design is filed, the part to be protected shall be indicated in the brief explanation when necessary."* It is not clear about under what circumstances such an indication is needed. The clearer explanation on this in the Implementing Regulations or in the Examination Guidelines should be provided. The explain when such an indication is needed and when it is not, using drawing examples in the Examination Guidelines should be provided. In the drawing examples of cases where the indication is needed, the examples of words or	Depending on the examiner, there may be difference in the decision on whether an indication in "the brief explanation" is needed or not. Therefore, it is necessary to make clear when such an indication is needed. Since, it is difficult to adequately understand designs only through written explanation, examples should be given in the Examination Guidelines. It is necessary for applicants to understand how to describe the part to be protected. Therefore, examples of words or sentences in "the brief explanation" should be given.

	sentences in "the brief explanation" should be provided.	
Item 1 of Rule 76	*Unless otherwise agreed, when a service invention-creation is achieved, the entity to which its inventor or creator belongs shall give him/her reward and remuneration in accordance with Article 15 of the Patent Law.* *However, unless otherwise agreed, if a patent right on the service invention-creation is transferred to a third party, the entity shall give reward and remuneration based on profits gained by the entity.* Thus, the sentence "However, unless otherwise agreed, if a patent right on the service invention-creation is transferred to a third party, the entity shall give reward and remuneration based on profits gained by the entity." should be added at the end of this paragraph.	If the entity transfers the service invention-creation to a third party, it will be impossible or extremely difficult for the entity to find out how the third party obtains and uses a patent right on the invention-creation. In such a case, the entity will no longer be an "entity to which a patent right is granted" as in Article 15 of the Patent Law. The third party to whom the service invention-creation is transferred does not have a contractual relationship with the inventor nor is an "entity" to which the inventor belongs. Therefore, the third party is not obliged to give reward or remuneration.
Rule 79	*The administrative authority for patent affairs referred to in the Patent Law and these Implementing Regulations means the department responsible for the administrative work concerning patent affairs set up by ~~the people's government of any province, autonomous region, or municipality directly under the Central Government, or by the people's government of any city which consists of districts, the people's government of any prefecture-level city which consists of districts, or the people's government of any county-level city which is authorized by law~~ the people's government of any province, autonomous region, or municipality*	While trademark cases and certain patent cases such as passing-off are relatively easy to be understood in detail and to be judged, patent infringement cases are often very difficult and complicated, which necessitates highly specialized knowledge and experience. Therefore, specialized departments directly under the State control should only be allowed to deal with patent affairs. If more departments, even departments of regional governments are allowed to handle patent affairs, it is possible that there will be inadequate judgements due to insufficient experience or knowledge, which could affect legal certainty or predictability. According to Article 69 (2) of the current Patent Law, the administrative authority for patent affairs has the power to interrogate the parties, perform on-site inspection,

	directly under the Central Government, or by the people's government of any city which consists of districts, has a large amount of patent administration work to attend to and has the ability to deal with the matter. This revision should not be made.	product inspection etc. If a patentee abuses this system with the intention of obtaining information from other companies, there is no guarantee that such a case can be judged adequately by a department with insufficient experience or knowledge. Therefore, the State should be responsible for establishment of an organization that has such a strong power.
Item 4 of Rule 85	*The compensation of the term of a drug patent shall be given to those patents related to new drugs of chemical drugs, biological products and traditional Chinese medicine which are approved for marketing in China, covering new drug products, preparation methods or medical uses, where the term compensation requirements of drug patents are met.* *The new-drug-related patents referred to in the previous paragraph refer to patents related to active ingredients of new drugs approved for marketing in China as innovative chemical drugs (化学药注册按照化学药创新药), improved chemical new drugs (化学药改良型新药), innovative biological drugs (生物制品注册按照生物制品创新药), improved biological drugs (生物制品改良型新药), innovative traditional Chinese drugs (中药注册按照中药创新药), and improved traditional Chinese drugs (中药改良型新药) as classified in Article 4 of Drug Registration Rule (药品注册管理办法).* ~~*of new drugs approved for marketing for the first time by the drug supervision and management department under the State Council*~~*. The new drug patents of traditional Chinese*	The current article provides CNIPA with discretion whether or not to grant drug patent term compensation even though “when the term compensation requirements of drug patents are met”. Such discretionary approach brings unpredictability of the patent term and discourages the development of innovative therapeutic R&D in the country. Therefore the drug patent term compensation “shall” be provided when the term compensation requirements are met. The timing of approval for marketing by the CFDA is beyond the control of an applicant. According to the DRR, a person can make a request for registration of a generic drug within two years before the expiry of the relevant patent. It is possible that a generic drug is registered earlier than the CFDA's approval for marketing of a new drug. In such a case, the application could be rejected on the ground that it is no longer a new drug. If such a situation is tolerated, it will be difficult to sufficiently recover investment in R&D, which could discourage further investment in R&D. We encourage CNIPA to specify the category of new drugs based on the classification ruled by DRR. In addition, CNIPA shall clarify that the “new drug” means “new-to-China”, but not “new-to-the world”. “New-to-the-world” approach erodes the motivation of innovative drug makers to early entry to the Chinese market.

	medicine include patents related to innovative drugs of traditional Chinese medicine and patents related to improved new drugs of traditional Chinese medicine with added functions/indications. The statement "of new drugs ... under the State Council" in the first sentence of the second paragraph should be amended as indicated above.	
Item 6 of Rule 85	*During the period of the compensation the term of a drug patent, the scope of patent protection shall be limited to the new drug approved for marketing by the drug regulatory department under the State Council and to the approved (including initial and later approved) indication for the new drug.* *The patent rights during period of the compensation the term of a drug patent shall have the same rights and obligations as those before such supplement.*	The scope of the patent rights during the compensation period shall encompass the later - approved indication of such new drug in addition to its initial approved indication.
Item 7 of Rule 85	*Where the patentee requests the compensation of term of drug patent, it or he shall file a request for the term compensation for drug patent within three months from the date of approval of the drug marketing approval application, attached with relevant certifying documents, and the drug and its patent upon the request shall meet the following conditions:* *(1) where a drug has multiple patents concurrently, the patentee can request to give the term compensation for drug patent to such multiple patents;*	(1) When there are multiple patents eligible for the term compensation for drug patent, CNIPA shall allow patentee to file the request for term compensation for all such patents. As same as in the US, when more than one patents are allowed for term compensation as a result of the examination, CNIPA can order the patentee to select one patent that to grant the term compensation. (4) The timing of disposition by law/regulations is beyond the control of an applicant. It will be really hard for the applicant if they are not allowed to file a request for an extension of the term merely because the remaining term happens to be shorter than six months.

	(2) where a patent involves multiple drugs concurrently, the request for term compensation for drug patent can be made for only one drug for the patent; *(3) the patent has not been granted the term compensation for drug patent yet~~;~~* *~~and~~* *~~(4) the remaining protection term of the patent for which the term compensation for drug patent is requested is not shorter than six months~~.* Thus, clause (4) should be deleted.	If an extension of the term is not available at all due to the timing of disposition, it will be difficult to sufficiently recover investment in R&D, which could discourage further investment in R&D. If CNIPA will keep the requirement (4), we encourage it to provide a remedy provision to allow the patentee to file the request for the term compensation for drug patent, even the remaining term of the patent is shorter than six months, if i) the patentee submits a notification to CNIPA of its intention of filing the request for the term compensation based on a marketing approval of a drug which is still under examination by the authority and the approval is expected to be obtained during the last six months of the patent term, and ii) the patentee files the term compensation of a drug patent after obtaining the marketing approval of the drug and before the expiry of the patent.
Item 5 of Hague specials	*Where the publication by the International Bureau of the international application for design includes one or more priorities, a written statement is deemed to have been made under Article 30 of the Patent Law.* *Where the applicant of the international application for design claims the right of priority, it or he shall submit a copy of the patent application filed the first time within two months from the date of publication of the international application.* ***If the Patent Administration Department under the State Council receives a copy of the earlier application through electronic transmission or in any other manner, based on an arrangement with the Receiving Organization, the copy of the earlier application shall be***	According to Rule 31 of the current Implementing Regulations, it is possible to submit the priority documents "through electronic transmission or in any other manner." Such provision is not found here. Electronic transmission or other means should be usable as under Rule 31 in order to promote the filing of applications under the Hague Agreement.

	deemed to have submitted by the applicant after being certified by the Receiving Organization. *Where the applicant recited in the copy of the earlier application document is inconsistent with that of the later application, the applicant shall submit relevant certifying documents. If no such document is submitted at the expiration of the time limit, the right of priority shall be deemed not to have been claimed.* Thus, the sentence "If the Patent Administration Department ... by the Receiving Organization" should be inserted after the first sentence.	