General Introduction to the Third Revision of the Patent Law of the People's Republic of China and Its Implementing Regulations

(for reference only)

1. Background and the Process of the Revision

The Patent Law of the People's Republic of China first entered into force on April 1st 1985, and was amended in 1992 and 2000 respectively. With the development of situations home and abroad, further improvement of China's patent legal system was required: on one hand, the 17th National Congress of the Communist Party of China put forward the target of enhancing the capacity of indigenous innovation and building an innovative country, and the State Council formulated the Outline of National Intellectual Property Strategy; on the other hand, the Doha Ministerial Meeting of WTO adopted the Doha Declaration in 2001, and the General Council of WTO adopted the Protocol amending the Trade-Related Intellectual Property Agreement in 2005. The Declaration and the Protocol allow the members of WTO to surpass the limits of TRIPs Agreement, and grant compulsory license of drug patents under certain circumstances. Besides, as the Convention on Bio-diversity provides principles on protecting the genetic resources by patent system, it is very important for China, as a country with abundant genetic resources, to revise its patent law, in order to implement the right endowed by the Convention.

The SIPO of the People's Republic of China initiated the revision process in 2005, conducted comprehensive researches, and released the first draft of the amendments for public comments in August 2006. In December 2006, the draft law was submitted to the State Council. On August 8th of 2008, the State Council submitted the draft law to the Standing Committee of National People's Congress for review, and later that month, the Standing Committee of the 11th National People's Congress convened the 4th meeting to review the draft amendment of the patent law and other laws. Since then, the draft amendment of the patent law had been put on the website of the National People's Congress for public soliciting of opinions. On Dec. 27th 2008, the 6th meeting of the Standing Committee of the 11th National People's Congress adopted the Decision on Revising the Patent Law of the People's Republic of China. The newly revised patent law came into force on Oct. 1st 2009.

SIPO submitted the Draft Amendment for Review of the Implementing Regulations of the Patent Law of the People's Republic of China to the State Council in February 2009. The State Council reviewed the draft in December 2009, and then promulgated the Decision of the State Council on Revising the Implementing Regulations of the Patent Law of the People's Republic of China in January 2010. The revised Implementing Regulations came into force on February 1st 2010, by which stage, the third revision to the Patent Law and its Implementing Regulations had been completed.

In the whole process of the revision, the Commission for Legal Affairs under the Standing Committee of the National People's Congress, the Office for Legislative Affairs of the State Council and SIPO had been firmly adhering to the spirit of making laws through democratic and scientific ways. Through dedicated researches, seminars, consultations with experts, on-line soliciting of opinions, and overseas surveys, opinions and suggestion from governmental authorities, enterprises, business associations, judicial authorities, experts and academicians were collected, which maintained the open and transparency of the whole process, and also ensured that the revised patent law and its implementing regulations could not only solve the problems China's facing, but also fully honored China's international commitments.

2. The Main Points of Revision to the Patent Law and Its Implementing Regulations

The main points of the revision to the patent law include the following: enhance the threshold of patentability; provide regulations on the protection of genetic resources; improve industrial design system; improve the confidentiality examination system for applications to a foreign country; invalidate the

designation of foreign-related patent agencies; increase SIPO's responsibility for the distribution of patent information; endow the right holders of industrial design the right of offering to sell, introduce a pre-litigation preservation measures, and include the cost of the right holder incurred for stopping the infringing act to the calculation of damage compensation; codify prior art defense; allow parallel import; provide exceptions of drug and medical apparatus experimentation; improve the compulsory license system, and so on.

The main points of revision to the implementing regulations include the following: provide supplementary requirements and detailed specifications for drafting patent application materials; specify the confidentiality examination system for applications to foreign countries; identify the definition of genetic resources, and prescribe on ways of disclosing the origin of genetic resources; enlarge the scope of preliminary examination for patent application; specify the patent right evaluation report system; improve compulsory license system; prescribe in detail the meaning and scope of the act of patent passing off; eliminate the maintenance fee for patent application, fees for requesting suspension of procedures, and some other items of charge; improve the reward and remuneration system for service invention-creations, and introduce the proscription of prioritizing the contracts between entity and the inventor or creator; adjust regulations on international applications entering Chinese national phase.

3. Explanations on Main Points of Revision

1) Confidentiality Examination for Applications to Foreign Countries

The confidentiality examination system has existed since the implementation of China's patent law in 1985. Article 4 of the Patent Law 2001 prescribes that where an invention-creation for which a patent is applied for relates to the security or other vital interest of the State, the application shall be treated in accordance with the relevant prescriptions of the State. Before the third revision, article 20 of the Patent Law 2001 prescribes that “[w]here any Chinese entity or individual intends to file an application in a foreign country for a patent for invention-creation made in China, it or he shall file first an application for patent with the Patent Administration Department under the State Council,…and comply with the provisions of Article 4 of this Law”; and Article 64 of the Patent Law 2001 prescribes that “[w]here any person, in violation of the provisions of Article 20 of this Law, files in a foreign country an application for a patent that divulges an important secret of the State, he shall be subject to disciplinary sanction by the entity to which he belongs or by the competent authority concerned at the higher level. Where a crime is established, the person concerned shall be prosecuted for his criminal liability according to the law”. Rule 8 of the Implementing Regulations 2001 set forth the specific procedures for confidentiality examination.

During past practice, problems were spotted with the above mentioned provisions. Firstly, the prescription on filing an application first in China leaves the applicants with no flexibility of choice; secondly, no legal liability was provided for filing first to a foreign country in violation with Article 20; thirdly, there was also confidentiality examination for applications of industrial design, which is actually not necessary; and fourthly, the procedure of confidentiality examination needed some improvements. In order to solve these problems, for the third revision, the following amendments were made: firstly, the wording of filing first the application in China was changed to must go through confidentiality examination first; secondly, prescribe clearly that there is no confidentiality examination for industrial designs; thirdly, clearly prescribe the legal consequence of filing in a foreign country without confidentiality examination, which is the patent application won't be granted in China, and criminal liability will be prosecuted under the condition of divulgence of national secrets; and fourthly, improved the procedures of confidentiality examination.

According to the provisions of the revised Patent Law and its Implementing Regulations, as long as the invention-creations are finished in China, no matter the applicant is Chinese entity or individual, or foreign entity or individual, the application must go through confidentiality examination in SIPO. But take into consideration that in some circumstances, applicants wish to apply in foreign countries first, or don't intend to apply in China, the revised Patent Law doesn't require the applicant to file a patent application on the same invention-creation in China. For those who wish to apply patent applications directly to foreign countries, the applicants shall first submit to SIPO a request for confidentiality examination and a description of the technical solution. If the applicants wish to file an application in China first, and then in foreign countries, the applicants can submit the request for confidentiality examination together with the application documents, or after the application date but before the applicants file the application in foreign countries. Besides, where applicants file with SIPO an international patent application in Chinese or English, it is deemed that the applicants submitted request for confidentiality examination at the same time.

After receiving the request for confidentiality examination, SIPO will send a notification of confidentiality examination to the applicants if SIPO believes that the application for invention or utility model might involves with State security or major interest, and therefore needs to be kept secret. Otherwise, if the applicant doesn't receive the notification of confidentiality examination within four months from the date of submitting the request, it is deemed that the applicant can file applications in foreign countries. For those applications of which the notification of confidentiality examination has been sent, SIPO will make timely decision on whether the application shall be kept secret. If the applicant hasn't received the decision made by SIPO within 6 month from the date of submitting the request, it's deemed that the applicants are allowed to file applications to foreign countries.

Currently, countries like the United States of America, India, Singapore, Australia, New Zealand, United Kingdom, France, Germany, Italy, the Netherlands, Israel and Russia all have confidentiality examination or prosecution procedures for applications to foreign countries.

Past practices prove that the procedure of confidentiality examination doesn't pose irrational hindrance to the applicants for applications to foreign countries. For those who submit the request for confidentiality examination together with the application documents, SIPO sends, together with the notification of the receiving of the application. The notification of either approving or suspending to file applications to foreign countries. Statistics show that, for those who submit the request for confidentiality examination after applying patent application in China or submit the request in the form of technical solution descriptions, the average pendency is 30 days from submitting the request to issue the first notification. The average pendency for confidentiality examination of international patent applications is 2 to 3 weeks, which is far shorter than the prescribed timeline of 4 and 6 months.

2) The Disclosure of the Direct and Original Source of Genetic Resources

The Convention on Bio-diversity (CBD) prescribes that the utilization of genetic resources shall follow the principles of State Sovereignty, Prior Informed Consent and Benefit Sharing, and it clearly stipulates that the patent system shall facilitate, instead of hindering, the protection of genetic resources. Currently, developing countries, who enjoy rich genetic resources like India and Brazil, as well as developed countries like Switzerland, Norway and Denmark, have already adopted protection of genetic resources through patent legal system. In order to protect China's rich genetic resources, prevent the illegitimate acquisition and utilization of genetic resources to conduct research and studies and thereby obtain patent right, based on the above mentioned principles of CBD, Article 5 and 26 of the amended Patent Law require the disclosure of direct and original sources of the genetic resources in patent application, and

clearly stipulate that the patent will not be granted for invention-creations derived from the illegitimate acquisition or utilization of the Chinese genetic resources. For example, according to the provisions in the Animal Husbandry Law of People's Republic of China and the Measures of People's Republic of China for the Examination and Approval of Entry and Exit and Foreign-Related Cooperative Research and Utilization of Livestock and Poultry Genetic Resources, the export of livestock and poultry genetic resources listed on China's protection list must go through relevant examination and approval procedure. Where an invention-creation is derived from the livestock and poultry genetic resources listed, if it doesn't go through the examination and approval procedure, this invention-creation cannot be granted a patent right.

The genetic resources referred to in the amended Patent Law mean the material obtained from such as human body, animal, plant, or microorganism which contains functional units of heredity and is of actual or potential value. Though the CBD doesn't make reference to the human genetic resources, taking into consideration that in reality, the illegitimate utilization of Chinese human genetic resources to the R&D of medicine has happened, the Implementing Regulations of the Patent Law explicitly includes the human genetic resources. Considering the fact that in many cases, the invention-creation do utilize the biological resources but not the hereditary function of the resources, the Implementing Regulations define that the “invention-creation is developed relying on the use of the genetic resources” referred to in the amended Patent Law means that the invention-creation is developed relying on the use of the heredity function of the genetic resources.

Where an application for patent is filed for an invention-creation, the development of which is relying on the use of genetic resources, the applicant shall indicate that fact in the request, and fill in the forms to disclose the direct and original sources of the genetic resources. For the direct sources of the genetic resources, the applicant shall provide information, such as the time, location and ways of acquiring the genetic resource and its providers; for the original sources of the genetic resources, the applicant shall provide information, such as the time and location of collecting the genetic resource and the collectors.

3) Improvement of the Compulsory License System

The amended Patent Law makes improvement on the compulsory license system, in accordance with the Paris Convention, TRIPs Agreement and the Protocol amending TRIPs Agreement.

As stipulated in the amended Patent Law, an entity or individual which is qualified to exploit the invention or utility model may submit a request for compulsory license with SIPO, “where the patentee, after the expiration of three years from the date of the grant of the patent and the expiration of four years from the date of filing, does not or does not sufficiently exploit the patent without any justified reason”. The non-exploitation of its or his patent means that the patentee does not exploit its or his invention or utility model in China, by the means of manufacturing, offering to sell, sell, utilizing or importing, etc.. Importing the patented product or obtaining product by the patented process, by the Patentee and/or the licensee shall be deemed as exploitation of its or his patent. The insufficient exploitation of patent means the manner or scale of the exploitation of patent by the patentee and/or the licensee authorized by it or him cannot satisfy the demands of the domestic market for the patented product or patented process. Under the circumstances of non-exploitation or insufficient exploitation, the entity or individual requesting a compulsory license shall furnish proof to show that it or he has made requests for authorization from the patentee to exploit its or his patent on reasonable terms and conditions, and such efforts have not been successful within a reasonable period of time. The exploitation of any compulsory license shall be executed predominately for the supply of the domestic market.

Furthermore, the amended Patent Law provides that the SIPO may grant compulsory license to exploit the patent for invention or utility mode, upon the request of an entity or individual which is qualified to exploit the invention or utility model, where the exercising of the patent right by the patentee is legally determined as an act of monopoly, for the purposes of eliminating or reducing the adverse effects of the act on competition.

The Protocol amending the TRIPs Agreement, adopted by the WTO General Council in December 2005 prescribes that, in order to assist members having insufficient or no manufacturing capacities in the pharmaceutical sector to address the public health problems, WTO Members may grant compulsory license to manufacture and export patented pharmaceutical to such members. China ratified the Protocol in October 2007. To implement the Protocol, Article 50 is added to the Chinese Patent Law, enabling SIPO to grant compulsory license to patented pharmaceuticals, for the purpose of exporting to the eligible states and areas.

By June 1, 2010, none compulsory license had been granted by the Chinese authority.

4) Reward and Remuneration for Inventors or Creators of Service Inventions-Creations

Reward and Remuneration mechanism for Inventors or Creators of Service Inventions-Creations is one of the important components of the Chinese Patent Law. According to the Article 16 of the Patent Law, “entity that is granted a patent right shall award to the inventor or creator of a service invention-creation a reward and, upon exploitation of the patented invention-creation, shall pay the inventor or creator a reasonable remuneration based on the extent of spreading and application and the economic benefits yielded”. This remains intact in the amendment.

Similar provisions can be found in the patent laws of Germany, UK, France, Sweden, Japan and Korea, stipulating explicitly the remuneration, in addition to the agreed salary, for inventor or creator employees. The specific standard of reward and remuneration set forth by the previous Implementing Regulations of the Patent Law was only applicable to state-owned enterprise, while other Chinese entity can implement by “make reference thereto”. With the purpose to ensure the independent management of enterprises, while at the same time, safeguard the legitimate interest of the inventors and designers, and to establish a fair competition environment, the amended Implementing Regulations no longer make difference among enterprises, and allow enterprises to enter into a contract with the inventor or creator on the manner and amount of the reward and remuneration. This could be fulfilled either as included in the employment contract or as stipulated in the in-house regulations, by monetary or other means. The amount of reward and remuneration can be lower than the one indicated in the Implementing Regulations, as long as it is reasonable. The Implementing Regulations will rule only when there is no such contract or consensus. This provides both the enterprises and the inventors and designers a right of fair negotiation on reward and remuneration for service inventions and creations, maintaining an appropriate balance between the two parties.

According to the Implementing Regulations, the “sum of money prize for a patent for invention shall not be less than RMB 3,000 Yuan; the sum of money prize for a patent for utility model or design shall not be less than RMB 1,000 Yuan”, and after exploiting the patent for invention-creation, the enterprises shall “draw each year from the profits from exploitation of the invention or utility model a percentage of not less than 2%, or from the profits from exploitation of the design a percentage of not less than 0.2%, and award it to the inventor or creator as remuneration. The entity may, as an alternative, by making reference to the said percentage, award a lump sum of money to the inventor or creator as remuneration once and for all. Where any entity to which a patent right is granted authorizes any other entity or individual to exploit its

patent, it shall draw from the exploitation fee it receives a percentage of not less than 10% and award it to the inventor or creator as remuneration".

5) Enhancement of the Threshold of Patentability

The amended Patent Law makes an appropriate adjustment on the patentability requirements, introducing the "absolute novelty" standard, instead of the previous "combined novelty" one. The absolute novelty standard means that prior art and prior design known to the public before the date of filing by way of public disclosure in publications, public use or any other means in China or abroad would destroy the novelty of an invention, and therefore make it impossible for the said invention to obtain patent protection in China.

Meanwhile, in order to raise the quality of design patent, a requirement similar to "inventiveness" in patents for inventions and utility models was added for design patent, i.e. the design shall be substantively different from the prior design or a combination of the feature of the prior design.

6) Reinforcement of Patent Protection

For purpose of an effective ceasing of infringement act, as well as a safeguard of the legitimate interest of the patentee, a pre-litigation evidence preservation framework is added in the amended Patent Law. Under the framework, for evidence that will possibly lose or be hard to be collected if not preserved before the litigation, the patentee may submit a request with the court to preserve the evidence before the litigation is brought.

The amended Patent Law adds a provisions that no entity or individual may, without the authorization of the patentee, offer to sell the product incorporating its or his patented design. Hence, when the design patent infringing product was displayed in shop windows, promoted in advertisements or exhibited on expositions or exhibition fairs, the patentee is entitled to request the infringer to cease infringement act and pay compensations.

The damage compensation system has also been improved. Taking into consideration the difficulties in calculating the amount of damage compensation in patent infringement, the amended Patent Law provides that "where it is difficult to determine the losses suffered by the right holder, the profits the infringer has earned and the exploitation fee of that patent under a contractual license, the people's court may award the damages of not less than RMB 10,000 Yuan and not more than RMB 1,000,000 Yuan in light of such factors, as the type of the patent right, the nature and the circumstances of the infringing act. Moreover, the amended Patent Law explicitly includes the reasonable expenses of the right holder incurred for stopping the infringing act into the amount of compensation for the damage, such as the attorney fee and the investigation expense. With this inclusion, the patentee may be provided with a better protection at lower cost.

7) Acts Not Deemed As Patent Infringement

To encourage free trade, and safeguard the interest of consumers, the amended Patent Law allows parallel import. If the patented product or product obtained directly by patented process has been put on a foreign market by the patentee or licensee, other entity or individual are entitled to import the product and put it on the Chinese market, without a prior authorization of the patentee. Such amendment in the Patent Law is in lien with the TRIPs Agreement, taking into consideration the flexibility provided by the Article 6 of the TRIPs, which allows WTO member to make its own decision on the exhaustion of right..

Besides that, the amended Patent Law introduces exception of drug and medical apparatus experimentation. Manufacture, import or use of a patented drug or patented medical apparatus by any person in order to acquire information necessary for regulatory approval will be deemed as an exception

to patent infringement. This will enable the manufacturers of pharmaceutical or medical apparatus to start earlier the procedure for approval and examination, make it possible for the patented drug or medical apparatus to be launched into market quickly after the expiration of the patent term, and therefore, ensure that the public can have access to drug and medical apparatus at low price.

It was so proposed, in the process of amendment, that an extension of protection term of drug patent shall be introduced. The proposal was not accepted by the legislative authority due to the following reasons:

(1) Article 33 of the TRIPS provides that the patent term is 20 years at least. Except for the said provisions, the TRIPs does not impose on the WTO members any obligations of extending the drug patent term.

(2) Relevant statistics indicates that almost all patented products will undergo a sharp decrease in the price upon expiration of the patent term, and thus the drug patent term has a direct bearing on the cost and opportunity for the 1.3-billion population of China to get drugs. Therefore, it is premature, for the time being, to extend the drug patent term.