NEW PRC PATENT LAW FROM A LIFE SCIENCES INDUSTRY PERSPECTIVE

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After more than three years of preparatory work, the revised PRC Patent Law ('the New Patent Law') was finally promulgated on 27 December 2008. The New Patent Law will enter into force on 1 October 2009.

Apart from the changes to the general provisions of the New Patent Law described in the first part of this article, changes to the patent regime that will mostly affect life sciences companies will be considered in relation to genetic resources-based patents, compulsory licences, parallel imports and the Bolar provision.

General Amendments to the Current Patent Law

The New Patent Law drastically modifies several existing concepts under Chinese law and introduces some new concepts.

Confidentiality Review in case of Patent Applications in a Foreign Country

To apply for a patent in a foreign country for an invention or a utility model developed in China, the applicant first has to apply in advance to the State Council for a confidentiality review.1 Subject to this examination, it may then directly apply for a patent in a foreign country or region. Violation of this provision will trigger prohibition from applying for such a patent in China.

This provision forces, to some extent, the initial application for a patent or utility model developed in China to be in China. Although it is aimed at protecting Chinese intellectual property and enhancing the patent-producing capacity of the PRC, this obligation in fact restricts foreign investment companies from developing a patent or utility model in China. The confidentiality review procedure will undoubtedly increase the burden and risk of making a first application for a patent in China.

Novelty of Industrial Design

The novelty criterion of an industrial design has been significantly modified. The current Patent Law applies the principle of 'relatively absolute novelty', which means that novelty of an industrial design requires the design to be not identical or similar to any industrial design that has been published in China or abroad, or that has been publicly used in China prior to the application date. Therefore, when determining the absence of novelty, the current Patent Law follows the principles of 'priority of use in China' and 'priority of publication in China and abroad'. Under the current Patent Law, the novelty of an industrial design will not be lost if it has been previously used abroad, provided that such use was not in a written publication. Consequently, if a foreign industrial design right holder has only displayed its design in a local exhibition abroad, without making any written publication in China or elsewhere, a third party is entitled to register an identical or similar industrial design in China, because the design is still novel in China.

The New Patent Law remedies this shortcoming and also protects the priority of use abroad, even if not published in writing, by introducing the terminology of an 'existing design', which refers to designs known to the public in China and abroad prior to the application date. The New Patent Law further provides that an industrial design shall not be the same as an existing design or an unpublished earlier application. This modification will offer foreign companies significant protection.

Facilitation of Industrial Design Application Procedure

The New Patent Law allows the applicant to apply for either one design or a series of designs for one product, whereas under the current Patent Law, the applicant has to apply for each design in the series separately, which increases workload.

Prohibition of Certain Industrial Design Applications

The New Patent Law prohibits applications to register a simple logo or industrial layout as an industrial design, where such logo or industrial layout serves as identification. Such provision implies that an applicant may no longer protect his logo both as a trade mark and a design.

Patent Co-ownership

The PRC Contract Law contains provisions related to technology co-developed by several parties and grants a right to apply for a patent for co-developed technology. However, there is no precision on the rules relating to the exercise of rights over co-owned patents. The Contract Law provides that, unless otherwise agreed between the parties, the right to apply for a patent for an invention co-developed between the parties shall be co-owned by the parties. If one party wishes to transfer the application right for such patent, the other parties have the pre-emptive right to purchase it.

The New Patent Law contains a new provision relating to the exercise of rights over co-owned application rights of a patent or of a co-owned patent: patent co-applicants or patent co-owners should reach agreement regarding the exercise of right of patent. In the absence of such agreement, each of the co-owners is entitled to implement the patent or grant a non-exclusive licence of the patent to third parties, and the benefits arising therefrom shall be distributed between the co-owners. The New Patent Law also provides that other rights that are not covered by the above provision (for example, the right to participate in legal proceedings relating to co-owned patents or the right to grant an exclusive licence) shall not be exercised without the prior consent of all co-owners.

However, the provisions of the New Patent Law do not clearly specify the co-owned application right of a patent and this therefore creates a conflict with the Contract Law. For instance, the Contract Law further provides that if one party waives its right to apply for a co-owned patent, the other party or parties have the right to apply for such patent and the party which waives the application right of such patent has the right to use such patent free of charge. However, if a party that co-develops a technology refuses to apply for a patent, none of the other parties may apply for a patent. According to the New Patent Law, the right to waive the application right of a co-owned patent and the right not to apply for patent for a co-developed technology shall also be subject to the approval of the other co-owners. This will be clarified in the Implementing Rules of the New Patent Law.

Retroactive Force of Interim Measures

The current Patent Law provides that if a patent is declared null, such decision will not retroactively affect the validity of (i) any judicial or administrative decision relating to such patent which has already been enforced before the declaration of nullity, or (ii) patent licences or transfer contracts that have already been performed before the declaration of nullity, except in case of bad faith of the patent right holder.

The current Patent Law does not explicitly exclude any procedural decision, such as injunctions or interim measures for conservation of assets, which means that a patent right holder may freely take action to prevent a third party from manufacturing or distributing the products or processes allegedly in violation of its patent, even if such patent is subsequently declared void. The New Patent Law seeks to clarify this issue and excludes any procedural decisions from loss of retroactive force. Such modification enables those companies against whom procedural measures have been adopted, to claim for damages against the patent right holder if his patent is eventually declared void.

Defence based on Existing Technology or Design

Article 62 of the New Patent Law explicitly provides that in case of patent infringement, if the defendant can prove that the technology or design it owns or uses falls within the scope of existing technology or existing design, no patent infringement occurs. Such provisions are not available under the current Patent Law. Only a judicial interpretation by the Supreme Court dating back to 2001 mentions terms similar to 'existing technology', that is, 'technology publicly known'. This judicial interpretation stated that courts may decide not to suspend the procedure of patent infringement if the defendant can prove that the technology it used has already been in the public domain prior to the application date of the plaintiff's patent. However, this judicial interpretation does not assert whether or not a patent infringement is constituted in such a case. In practice, many local courts have already accepted a defence based on such publicly known technology or design. The New Patent Law therefore provides an underlying principle for these kinds of judgments.

Enhancement of Patent Enforcement

The New Patent Law enhances patent enforcement and introduces injunction measures and pre-trial measures, including preservation of assets and evidence, which were previously only provided for in the judicial interpretations of the Supreme Court.

Furthermore, the New Patent Law details powers granted to patent enforcement authorities which are not clearly provided in the current Patent Law. The patent enforcement authorities have the right to interrogate parties, make on-site inspections, inspect and copy all related contracts, invoices, accounting books or other materials and confiscate or seal counterfeited products.

Increase of Sanctions and Compensation Criteria

In case of administrative sanctions, the New Patent Law increases the current fine to up to four times the illegal gains (three times under the current Patent Law) or RMB 200,000 (RMB 50,000 under the current Patent Law) if no illegal gains can be shown.

Furthermore, the New Patent Law modifies the calculation of damages in case of patent infringement in civil proceedings. Compensation shall be assessed in the following order:

(i) actual losses suffered by the patent right holder;

(ii) if actual losses cannot be determined, illegal profits obtained by the infringer;

(iii) if neither (i) nor (ii) can be determined, an amount equivalent to a reasonable multiple of royalties charged by the patent right holder; and

(iv) if (i), (ii) or (iii) cannot be determined, the court can determine damages up to RMB 1 million (RMB 500,000 under the current Patent Law).

The New Patent Law does not define a 'reasonable multiple' in respect of (iii) above, whereas the current implementing rules of the Patent Law suggest a multiple of one to three. The draft implementing rules of the New Patent Law do not make such specification either. It will be interesting to see what a 'reasonable multiple' will be in respect of (iii) above.

The New Patent Law further clarifies that reasonable costs incurred by the patent right holder to cease patent infringement shall also be compensated, whereas under the current regulations such compensation is left to the discretion of the local court. However, the New Patent Law still does not clarify whether or not legal fees can be considered as part of the above costs. Our interpretation is that they cannot.

Amendment Relating to the Life Science Industry

Genetic Resources

The New Patent Law has introduced for the first time a compliance requirement and a disclosure obligation in applications for patents based on genetic resources.

First, Article 5 provides that no patent shall be granted if an invention is based on genetic resources obtained or used in violation of any laws or administrative regulations.

Where Article 27.2 of the TRIPs Agreement only provides that '*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality* …', Article 5 sets out a general reference to 'laws and regulations', which could imply that there will be more detailed laws and regulations on this matter in future.

Secondly, Article 26 of the New Patent Law requires the applicant to disclose and explain the direct and original source of the genetic resource. If the applicant is not able to disclose such source, reasons must be provided.

This obligation is in line with the international trend of introducing disclosure obligations. For example, the Swiss Patent Law of 2008 includes such an obligation. In addition, 110 WTO members, including China, proposed in the Doha negotiations in July 2008 considering including a disclosure obligation in the TRIPs Agreement. The disclosure obligation is also welcome for better transparency in the access to and benefit sharing of genetic resources, according to the Convention on Biological Diversity and the Bonn Guidelines on Access and Benefit Sharing. It is also believed that this disclosure obligation will improve the patent examiners' work.

However, Article 26 triggers many questions as to implementation. How will the 'direct source' and 'original source' be defined? What reasons would be acceptable for not disclosing the original source? Such questions may lead to implementation uncertainties and life science companies must keep a close eye on these matters to ensure requirements are complied with before they apply for a patent.

Compulsory Licence

In addition to the circumstances of national emergency, an extraordinary state of affairs, public interest or major technical progress of prominent economic significance based on a patent, which was provided for in the former Patent Law, the New Patent Law adds new grounds on which the Patent Office may grant a compulsory licence for patents.

First, Article 48 provides that a compulsory licence may be granted where (i) a patentee fails to exploit or fully exploit his patent without any justifiable reason within three years of the patent grant date or four years of the patent application date, or (ii) the patentee has been exploiting the patent rights in a monopolistic manner.

It is noted that the wording of Article 48 is vague, which renders its application uncertain. At the very least, definitions of 'failure to exploit', 'justifiable reason' or 'monopolistic behaviour' need to be provided to avoid any detrimental effects to patent holders. How this provision will be combined with the Anti-monopoly Law that entered in force in August 2008 and the right of judicial and administrative process of Article 31(k) TRIPs is still unknown.

Secondly, Article 50 provides that for reasons of public health policy, the Patent Office has the right to grant Chinese companies licences for patented medicines to be manufactured and exported to countries or regions with which the PRC has concluded related international treaties.

This provision implements the Decision of the Amendment of the TRIPs Agreement (2005) ratified by China on 28 November 2007, which states that '*the obligations of an exporting Member under Article 31(f)* [according to which a compulsory licence shall only be granted for the supply to the domestic market of a Member] *shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)* …'. There is little doubt that China will be a prime candidate, in addition to countries like India, as a manufacturing power-house, to export medicines under a compulsory licence scheme. The New Patent Law, however, makes no reference whatsoever to necessary identifying measures such as labelling or marking to guarantee that the medicines will indeed be exported from China to eligible countries and not remain in China, be re-imported or sold in non-eligible countries.

Parallel Imports

The New Patent Law explicitly confirms that parallel imports are not considered to be a patent infringement.

Article 69 of the New Patent Law provides that the use, offer for sale, sale and importation of patented products or products made from a patented method, which have been sold by the patent right holder or the entity or individual authorised by the patent right holder, shall not be considered to be infringing.

Before the adoption of the New Patent Law, Chinese law did not contain such a provision. Without any legal basis, Chinese courts could inconsistently allow or condemn parallel importing. The extent to which patent right holders will consider adopting stock management schemes or trade mark protection strategies against repackaging, de-branding, co-branding and re-labelling is still unknown.

Moreover, it remains to be seen how an international exhaustion system can be effectively implemented in practice as long as the authorities require an original copy of an import product licence in China before issuing customs clearance. Currently, such a document is only granted to foreign manufacturing entities and not to any middleman or entity such as wholesalers. Finally, in many jurisdictions, export of patented products constitutes a breach.

Bolar Provision

The Bolar provision has also been incorporated into the New Patent Law. Article 69(5) provides that the manufacture, use and import of patented medicine or medical devices by someone other than the patent holder shall not be considered to be a patent infringement if such manufacture, use or import is solely for the purpose of obtaining administrative approval for the pharmaceuticals or medical device.

Unlike the EU Bolar exception clause that limits the purpose of the Bolar exception to a reduced application process for generics, the Chinese Bolar provision applies to new drugs and medical devices. Further, the provision does not seem to apply exclusively in the case of a market authorisation in China unlike in the EU.

In addition, it should be noted that China's drug approval authority, the SFDA, currently requires that the application for a generic of a patented drug can only be accepted two years prior to the expiration of the patent.

The New Patent Law brings clarity to the former patent regime, but many terms that have been used remain to be defined.

As a major emerging economy, China is striving to become an innovative country while facing major concerns such as accessibility to and affordability of medicines. The New Patent Law reflects this dilemma and as a result there are foreseeable difficulties in its implementation.

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1) Article 20 paragraph 1 of the New Patent Law.