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Chinese Patent-Law and Implementation Amendments Bring Key Changes, Interpretive Challenges

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For the past decade, the People's Republic of China (PRC) has developed a body of patent law that is helping make the country's regulatory environment more compatible internationally. The implementation of amendments to patent law and regulations is speeding the process. While these changes are welcome, uncertainties remain as to how China's new patent environment will affect current and prospective patent holders.

The Patent Law of the PRC was enacted in 1985, and then amended in 1992 and 2000 (collectively referred to as the "2000 Patent Law"). The most recent amendments were made in 2008 (the "2008 Patent Law"), and became effective on Oct. 1, 2009.

In December 2009, the Supreme People's Court (SPC), China's highest court, adopted a set of judicial interpretations regarding cases involving patent disputes (the "2009 Interpretation").

In the beginning of 2010, the Implementing Regulations of the PRC Patent Law (the "2010 Implementing Regulations") were amended accordingly to reflect the changes to the 2008 Patent Law. The 2010 Implementing Regulations took effect on Feb. 1, 2010.

This advisory summarizes some critical differences between the 2000 Patent Law and the 2008 Patent Law. We have noted the changes resulting from the new amendments to the 2010 Implementing Regulations, which went into effect in early 2010. We have also noted where the SPC's 2009 Interpretation falls short in light of the amendments.

Preliminary issues before filing a patent application

The 2008 Patent Law and 2010 Implementing Regulations clarify that a confidentiality examination applies to foreign companies and individuals within China, and expands the scope of employee rewards for in-service invention from state-owned companies to all businesses.

Confidentiality examination for foreign patent filing [1]

Under Chinese patent law, patents are divided into three categories: invention, utility model, and design. An "invention" is defined as any new technical solution relating to a product, a process, or improvement thereof. Here, the word "invention" is used to describe a particular type of patent application or patent and should be distinguished from an invention in the general sense, which is much broader in scope. A "utility model" is defined as any new technical solution relating to the shape, the structure, or their combination, of a product, which is fit for practical use. A "design" is defined as any new design of the shape, the pattern, or their combination, or the combination of color with shape or pattern, of a product, which creates an aesthetic feeling and is fit for industrial application.

Under the 2000 Patent Law, Chinese companies or individuals were required to file for a Chinese patent application for inventions made in China before they could file for a foreign patent application for such inventions. The 2000 Patent Law was silent on whether foreign companies or individuals were required to abide by this rule.

The 2008 Patent Law has changed this provision in two ways. First, for inventions or utility models made in China, Chinese companies or individuals are allowed to make foreign patent filings first, provided the filings pass a confidentiality examination by the State Intellectual Property Office (SIPO). The purpose of the examination is to prevent disclosure of information relating to national security or significant national interests. Second, the 2008 Patent Law specifies that the first rule also applies to foreign companies or individuals.

A confidentiality examination under the 2008 Patent Law is mandatory, regardless of whether an applicant intends to file its patent application in China first. If the applicant plans to file an application with a foreign patent office directly, it must submit its technical details to the SIPO for a confidentiality examination beforehand. An applicant who files first with a foreign patent office without a confidentiality examination will be denied patent rights in China. If the applicant plans to apply for a Chinese patent before filing a foreign patent application, an application for the confidentiality examination can be filed together with or after filing a Chinese patent application. An International Application under the Patent Cooperation Treaty (PCT) designating SIPO as the receiving office is deemed an application for the confidentiality examination.

The confidentiality examination process consists of two phases.

First, the SIPO must decide as soon as possible after receipt of the application for the confidentiality examination whether national security issues or other significant national interests are involved and whether a further examination is necessary. If the applicant does not receive any notice from the SIPO regarding further examination within four months after filing the application for the confidentiality examination, the applicant is free to proceed to foreign patent filing.

Second, if further examination is necessary, the SIPO must notify the applicant of such further examination. If the applicant does not receive a denial notice from the SIPO within six months after filing the application for the confidentiality examination, it is also free to carry out patent filings in foreign countries.

Crucial terms of the new confidentiality examination mechanism need to be clarified. The phrase "inventions or utility model made in China" is defined in the 2010 Implementing Regulations as "inventions or utility models of which the substantive content of technical solutions was completed in China." However, the 2010 Implementing Regulations do not provide further clarification to the meaning and scope of "substantive content."

In practice, clarifications of such crucial legal terms are usually made by the SPC, but the 2009 Interpretation contains no language in this regard and it is difficult to predict when clarifications will be officially published by the SPC. Until the meaning of "substantive content" is clarified, significant uncertainty remains for the new changes in the 2008 Patent Law.

Employee reward [2]

Under the 2008 Patent Law, patent rights related to in-service invention creation (e.g., an invention, utility model, or design created by an employee in completing a task or project on behalf of an employer or by using the employer's resources), belong to the employer; however, the employer must reward the employee for a *granted* patent. Before the 2010 Implementing Regulations, only state-owned companies were subject to the statutory reward requirement. The 2010 Implementing Regulations have expanded the scope to all types of employers, including both domestic and foreign employers regardless of their ownership.

The 2010 Implementing Regulations allow an employer and an employee to agree upon the standard for the reward. Alternatively, the employer may set forth the rules for such a reward in its internal regulations and policies.[3]

Otherwise, the default rule applies, according to which, the employer must (i) reward the employee at least RMB 3,000 for each invention patent, and at least RMB 1,000 for each utility model patent or design patent; (ii) remunerate annually the employee no less than 2 percent of its business profits derived from the exploitation of the patent for an invention patent or a utility model patent, or no less than 0.2 percent for a design patent; and (iii) pay no less than 10 percent of the royalty to the employee when the employer licenses the patent to a third party.

Changes to the patenting process

The 2008 Patent Law and 2010 Implementing Regulations address the issue of genetic resources for the first time, enhance the novelty requirement, and strengthen regulation regarding double patenting.

Genetic resources [4]

To regulate the increasing number of patent applications involving genetic technologies, the 2008 Patent Law addresses issues relating to genetic resources used in an invention patent. It provides that if the acquisition or use of genetic resources violates relevant laws and regulations in China, any invention using such genetic resources will be barred from patenting. Furthermore, an applicant must disclose the direct and original sources of such genetic resources, and if the applicant cannot identify the source, it must specify the reasons for failing to do so. The 2008 Patent Law does not seem to regulate genetic resources themselves, but rather the means for obtaining such resources.

Novelty requirement [5]

Under the 2000 Patent Law, novelty was not destroyed if an invention had already been used in foreign countries, as long as it had not been used in China or published anywhere in the world before its filing in China.

The 2008 Patent Law has adopted the "absolute novelty standard" by requiring that the invention must by no means be disclosed or used anywhere in the world, by the same applicant or by others, before the filing date in China, except for certain foreign applications to which the Chinese application claims priority. Unlike the U.S. novelty standard, a limited grace period of six months is allowed under the 2008 Patent Law.[6] The use of an invention in

foreign countries currently bars it from being patented in China.

Furthermore, under the 2000 Patent Law, an earlier application published after the filing date of a later application by the same applicant was not considered prior art with respect to the later application. This old standard was similar to that set forth in 35 U.S.C. § 102(e). The 2008 Patent Law extends the scope of prior art to include an applicant's own application, providing that anyone's disclosure of an invention in an earlier application will destroy the novelty of a later application on the same subject matter and bar the patenting of the later application.

With the intention of reducing "frivolous" patent applications, the 2008 Patent Law also applies the absolute novelty standard to utility model and design patents.

Double patenting [7]

Before the 2008 Patent Law, it was common for an applicant to apply for a utility model patent and then apply for an invention patent for the same invention, since a utility model patent required only preliminary examination, and was therefore much easier and quicker to obtain. Such applicants could get the invention patent later, as long as they would forfeit any right to the earlier-granted utility model patent.

This practice actually prolonged the protection period for an invention, since the protection period of a patent starts as of the filing date of the application from which the patent is granted. In order to resolve this issue, the 2008 Patent Law provides that an applicant may still apply for a utility model patent and an invention patent for the same invention, but these two applications must be filed on the same day. In other words, if the applicant files the invention patent application later than the utility model patent application, the invention application will be denied. The 2008 Patent Law maintains the "first-to-file" standard, which is similar to most jurisdictions and different from the "first-to-invent" standard in the U.S. Thus, when two applicants apply for the same invention, the earlier application will trump the later one regardless of who actually created the invention first.

Changes in the enforcement of patent rights

The 2008 Patent Law and 2010 Implementing Regulations set forth the principles of patent co-ownership, expand the scope of compulsory license, resolve the legislation conflict regarding the transfer of patents, provide two infringement exemptions, and enable an alleged patent infringer to raise a prior-art defense.

Co-ownership of patents [8]

Co-owners' rights to a patent were not covered in the 2000 Patent Law. The 2008 Patent Law has laid down several principles in this regard. First, an agreement between co-owners prevails. Second, in the absence of an agreement, a co-owner is entitled to exploit the patent and grant nonexclusive license of the patent to a third party provided that the royalty is shared with the other co-owner(s). Third, any other exploitations of the patent, such as exclusive license, must be agreed upon by all co-owners.

Compulsory license [9]

Generally, no one is allowed to use a patented invention or utility model without the patent owner's consent. However, under special circumstances, such as emergencies or public interest requirements, the SIPO may order the patent owner to grant a "compulsory license" of the patent to certain entities and/or persons. A compulsory license requirement is not applicable to design patents.

The 2008 Patent Law expands the scope of compulsory licenses and provides more detailed rules in this regard. Under this new law, the SIPO may grant a compulsory license of an invention patent or a utility model patent to a third party (i) if a patent owner has failed, without justification, to exploit or sufficiently exploit the patent within three years after the issuance of the patent or four years after the filing of the patent application, whichever is later; or (ii) if the exploitation of the patent is deemed monopolistic behavior[10] and the purpose of the compulsory license is to eliminate or reduce the adverse influence on competition caused by this monopolistic behavior.

Additionally, for public health purposes, the SIPO may grant compulsory licenses to manufacture, thus allowing export of patented pharmaceuticals to regions or countries covered by international treaties to which China is a signatory.

Compulsory licenses of patent relating to semiconductor technologies are only subject to regulations specified in provision (ii) and the public interest requirement.

There have been many concerns over the new compulsory license clause due to the ambiguity of the so-called "sufficient exploitation of patent" and the lack of a definition of "patented pharmaceuticals." The 2010 Implementing

Regulations aim to eliminate these concerns by clarifying that "sufficient exploitation of patent" means the ability to fulfill the domestic demand for the patented product, and that "patented pharmaceuticals" are any patented products or products directly obtained according to patented processes in the medical and pharmaceutical field, including diagnostic instruments as well as active ingredients.

Despite these attempts at clarity, ambiguities remain; for example, the standard applied to calculate the domestic demand is still unknown. Usually, such issues are addressed by the SPC in its judicial interpretation, but these are not covered by the 2009 Interpretation. Furthermore, it is noteworthy that, even though compulsory licenses have existed in the Patent Law of the PRC since its promulgation in 1984, none have ever been granted. Therefore, it could take a very long time before such issues attract the attention of the SPC and are finally clarified.[11]

Transfer of patents [12]

An applicant is entitled to certain rights, after applying for but before being granted a patent right, called "rights of patent application." Under the 2000 Patent Law, if a Chinese company or individual wanted to transfer either rights to a patent application or rights to an issued patent to a foreign company or individual, the transfer required government approval.

However, this old provision was in conflict with the Technology Import and Export Regulations, under which technologies are divided into three categories: prohibited, restricted, and freely transferable. Under these regulations, patent rights containing prohibited technologies are not allowed to transfer; patent rights containing restricted technologies require government approval; and patentees with rights containing freely transferable technologies should record the contracts between related parties with the government in order to obtain a transfer license.

In order to eliminate this conflict, the 2008 Patent Law removed the 2000 Patent Law's government approval requirement, stating that the transfer of rights to a patent application or patent from a Chinese company or individual to a foreign company or individual will be governed by relevant laws and administrative rules, e.g., the Technology Import and Export Regulations.

Infringement exemptions [13]

1) Parallel imports

In the international trade market, multinational companies often set different price points for their products in different markets. Parallel importers take advantage of the difference between a first price in a country (P1) and a second and higher price in another country (P2). They purchase products in the first country at price P1, import the products into the second country, and sell them there at a price that is usually between P1 and P2. Products sold in the second country are generally called "parallel imports."

The 2008 Patent Law explicitly allows parallel imports, stating that: "importing patented products or products obtained directly by operation of a patented process after such products have been sold by the patent owner or its authorized companies or individuals shall not be deemed as infringement to patent."

Before the 2008 Patent Law, the validity of such parallel imports was controversial, since the 2000 Patent Law did not address the issue of parallel imports. Those advocating the doctrine of "international exhaustion" argue that the patent owners' patent rights have exhausted internationally when their products are sold in an overseas market; therefore, the patent owners should no longer be entitled to protection under Chinese patent law.

Others advocating the "regional exhaustion" doctrine argue that the patent owners' patent rights only exhaust in the foreign countries where they sell their products, but not in China. Accordingly, parallel importers' importation of patented products constitutes infringement to the patent owners' patent rights in China.

The 2008 Patent Law adopts the doctrine of "international exhaustion" and allows parallel imports.

2) Regulatory approval exception

Drugs and medical devices must be approved by the government before they can be sold to the public, whether they are patented or not. Pharmaceutical companies must provide the required

technical data regarding the drugs and medical devices for such approval. In order to quickly bring generic products into the market to provide cheaper drugs or medical devices to the public, the 2008 Patent Law provides an express infringement exemption for activities that relate to obtaining the required information for regulatory approvals for drugs and medical devices.

Benefiting from this exception, generic pharmaceutical companies may start performing research and development (R&D) on and manufacturing patented drugs or medical devices before the expiration of relevant patents without infringing upon the patent owner's patent rights. This allows for the collection of required technical data for the aforementioned approvals as soon as possible.

Prior-art defense [14]

A common defense for an alleged infringer in a patent infringement suit is the invalidity defense: If a patent is proven invalid, there is no infringement. Before the 2008 Patent Law, once such a defense had been raised, courts would have to suspend the proceedings, because the Chinese Patent Reexamination Board (CPRB) is the sole authority for determining the validity of a patent.

This previous system was flawed, because there was no judicial certainty without the validity determination. It could take a very long time for the CPRB to make such a determination, and court proceedings could be put on hold infinitely.

The 2008 Patent Law allows an alleged infringer to defend the infringement claim in court by proving the technology or design it is using is in the scope of prior art, so as to avoid the time-consuming patent invalidation procedure and expedite the entire proceeding.

However, it is noteworthy that the prior-art defense, even upheld in court, does not affect the validity of the patent in dispute, as the CPRB remains the sole authority for invalidating a patent. Accordingly, the alleged infringers who did not successfully raise the prior-art defense may still be subject to infringement liability.

A court's determination that a patent falls under the scope of prior art could probably be used as evidence in the invalidation process before the CPRB, however it is not clear to what extent the CPRB will recognize such findings.

Conclusion

The 2008 Patent Law and 2010 Implementing Regulations change many aspects of patent administration in China, from preliminary issues to patent application to enforcement of patent rights. While these changes may improve patent protection in China, and thus bring it more into line with international norms, they also create new uncertainties as new concepts demand further clarification.

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FOOTNOTES

1 Article 20 of the 2008 Patent Law, Article 8 and Article 9 of the 2010 Implementing Regulations.

2 Articles 76, 77, and 78 of the 2010 Implementing Regulations.

3 According to Article 4 of PRC Labor Contract Law, internal regulations and policies must be approved by labor union or employee representatives, if such regulations and policies are related to remuneration and benefits.

4 Article 5 and Article 26 of the 2008 Patent Law.

5 Articles 22 and 23 of the 2008 Patent Law.

6 The grace period is the time after the date an invention is disclosed to the public during which the inventor can apply for a patent and not have the disclosure count as prior art against the inventor's application. The U.S. grace period is one year. No grace period is provided in Europe and many other jurisdictions. Under the new 2008 Patent Law, a grace period of six months is provided for disclosure in limited and recognized exhibits and meetings or disclosure by others without inventor consent. See Article 24 of the 2008 Patent Law.

7 Article 9 of the 2008 Patent Law.

8 Article 15 of the 2008 Patent Law.

9 Articles 48, 49, 50, and 52 of 2008 Patent Law, Article 73 of the 2010 Implementing Regulations

10 According to Article 3 of the PRC Antimonopoly Law, “monopolistic behavior” refers to monopolistic agreements between entities, abuse of dominant market position by entities, or concentration of entities that may eliminate or restrict competition.

11 Compulsory license is also related to the national standard regulation. The Interim Regulations on the Administration of Setting and Revision of the National Standard Involving Patent (Exposure Draft) published by the National Standardization Administration Committee (“Draft Interim Regulation”) in November 2009 for public discussion provides that, if a mandatory national standard necessarily concerns a patent, the patent owner shall grant license for free or according to an agreement with the government. If the patentee and the government can not reach an agreement, the government may grant a compulsory license of the patent. This provision, although is not effective yet, causes strong disagreement from multinational companies, as they worry their patents may be exposed to great uncertainty after the promulgation of the Draft Interim Regulation.

12 Article 10 of the 2008 Patent Law.

13 Article 69 of the 2008 Patent Law.

14 Article 62 of the 2008 Patent Law.