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Comments on Impact of PRC Patent Law Amendments to Pharmaceutical Industry

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The Legislative Affairs Office of State Council has published the *Draft of Amended PRC Patent Law (Draft for Review)* (hereafter the "**Draft**"), and will seek comments publicly till the New Year's Day of 2016. The **Draft** contains several amendments to *PRC Patent Law*, even including some changes on certain legal principles. Most of the amendments will influence all industries, and a portion of them will even have large influence over the pharmaceutical industry.

The Principles of Amendment

Any amendment made to law aims at following the development of social relations, thus there must be guiding principles for the amendment. It is therefore necessary to understand the background and guiding principles of law amendments, so as to better understand its impact to industries from a high level.

According to the State Intellectual Property Office ("**SIPO**"), the guiding principles for the amendments to *PRC Patent Law* are "to strictly enforce protection of patents, protect the legitimate rights and interests of innovators, and promote the implementation and exploitation of patents". In fact, amendments to pertinent Articles of the *PRC Patent Law* also reflect these principles.

According to the principles as mentioned above, the amendments made to *PRC Patent Law* will have different impacts on different pharmaceutical companies. On the one hand, to the enterprises which mainly produce low-tech generic drugs, if they do not pay enough attention to patent clearance before launching the production, they will be exposed to more severe consequences, including higher damage rewards and administrative fines. On the other hand, to the enterprises which have strong R & D capability and good tradition of IP strategy - represented by large multinational pharmaceutical group, they could expect to protect their

innovator drugs and other innovative outcomes more effectively through the a more effective patent protection system and thus enhance their competitive advantage in the market.

Amendments to Important Articles

a. Invention made through using the material and technical means of the employer will no longer be deemed as service invention

Item 4 of Article 6 of the **Draft** stipulates that "[A]s for invention-creation made by a person through using material and technical means of the entity to which it belongs, if the entity has not reached any agreement with the inventor/designer regarding ownership of the invention-creation, right to apply for a patent shall belong to the inventor/designer".

Before the amendment, the invention-creation made by an employee through using material and technical means of the employer would be regarded as a kind of service invention, and the right to apply for a patent would belong to the employer by default. However, said patent application right will belong to the employee due to the amended law. This is a significant and fundamental change which needs an eye on. In many industries, especially the pharmaceutical industry, it is rarely possible for an employee to make an invention independently without using the material and technical means (like the laboratory, know-how, etc.) of the employer. Therefore, in the future, it will become necessary for a company to reach special agreements with its employees (in the labor contract or specific contract) to clarify that any invention made by employees through using material and technical means of the company shall belong to the company.

b. The Patent Re-examination Board ("PRB") get its power enhanced and will have the right to review the re-examination and invalidation requests on its own initiative

Item 2 of Article 41 of the **Draft** stipulates that "[T]he Patent Re-examination Board reviews reexamination requests, and if necessary, it has the power to review whether the patent application meets other requirements set forth in this law." Similar principle also applies to review of invalidation requests, pursuant to amended Item 1 of Article 46.

The above amendment will significantly enhance the power of PRB. Due to lack of pertinent implementation rules, it is unclear at present whether PRB will have power to initiatively introduce evidence (such as prior arts) at its discretion to evaluate defects unmentioned in the reexamination/invalidation request. However, it seems that PRB will act in a way more similar to an administrative authority than a court, which means it will be placed in a more active and potent position in judging the validity of patents. As a consequence, taking the invalidation proceeding as an example, if PRB is given the power of prior art search, then prior art evidence submitted by the petitioner after the time limit will become still acceptable to PRB, which may

make it easier and more efficient in procedure to invalidate a patent. This is something worthy of attention from both innovator drug manufacturers and generic drug manufacturers.

c. The power of patent administrative department in raiding infringement is significantly enhanced, which provides another good option to patentees

According to Article 61 of the **Draft**, if a party refuses to perform the settlement agreement reached under mediation of the patent administration authorities (i.e. the local Intellectual Property Office), the other party may apply to the court to confirm the settlement agreement and enforce it. This amendment enhances the enforceability of such settlement agreement, differentiates it from an ordinary contract, and provides it with a power similar to a judicial mediation, although confirmation from a court is still needed.

Pursuant to Article 60 of the **Draft**, as to the willful infringements such as group infringement and repeated infringement, the patent administrative authorities are entitled to confiscate the infringing products, as well as parts, assemblies and molds/devices solely used for producing infringing products. As to repeated infringement, a fine may be imposed. This amendment grants local Intellectual Property Office power even stronger than the judicial system in attacking infringements. It is the situation in China that many infringers will put substantially the same infringing products into market again with a new model number. To such repeated infringers, it is obviously a heavy blow for the patent administrative authorities to confiscate their production facilities and products together with a large-amount fine.

In addition, according to Article 63 of the **Draft**, the patent administration department is also entitled to order the online service provider to repress the patent infringement ongoing on their websites. That is to say, in the future, if any product sold on the e-commerce websites like Taobao and JD is found constituting infringement, the local Intellectual Property Office can order these websites to pull such infringing product off the shelf, e.g., to disconnect hyper-link to the product.

The aforementioned amendments show that the local Intellectual Property Office's power and ability have been greatly strengthened. It is the fact that the local Intellectual Property Office still has no power to directly order the infringer to pay compensation to the patentee. However, viewing from the outcome, the measures taken by local Intellectual Property Office, such as seizing the infringer's products and devices, as well as imposing fines, will cause great and direct damage to the infringers in a swift way, not to say that the administrative action goes much faster than litigation at court. Therefore, we believe that once these drafted amendments are finally incorporated into the amended *PRC Patent Law*, local Intellectual Property Offices are likely to become powerful weapons for patentees.

However, it is to be noted that the administrative authorities also have their own limitations. Limited by its institutional setting and personnel structure, a local Intellectual Property Office

will not be as professional as a court in finding patent infringement, especially when it comes to pharmaceutical industry, in which field patents often involve complex technology. Furthermore, the administrative penalty decisions are not final, against which the infringer may bring up an administrative lawsuit. These factors may weaken the convenience of the administrative actions at some extent, and should be taken into the patentees' consideration in choosing the best way of enforcing the patents.

d. Rules regarding punitive compensation and spoliation of evidence are introduced, and both the lower and upper limits of statutory compensation amount are raised up, which significantly strengthen the judicial protection of patent rights

According to Items 1 and 2 of Article 68 of the **Draft**, for willful infringement, a punitive compensation can be determined from one to three times of the basic compensation, and the statutory compensation will be promoted to a range between RMB 100,000 and RMB 5,000,000, from the original range between RMB 10,000 and RMB 1,000,000.

Obviously, this amendment will significantly strengthen the judicial protection to patent rights. Firstly, the promotion to the statutory compensation will grant the judges more discretion in deciding the damage, who can determine a damage reward as high as RMB 5, 000,000 in case of severe infringement. The increased damage will better cover the patentees' costs and thus facilitate the right protection process. Also, punitive damage granted against willful infringement is expected to resolve repeated infringements.

In addition, Item 3 of Article 68 of the **Draft** also introduces rules regarding spoliation of evidence. Pursuant to the rules, if the defendant refuses to provide the financial materials it possessed which can prove the scale of infringement, the judge may determine the amount of damage reward by referring to the claims and pertinent evidence of the plaintiff. This amendment is particularly important to patentees in the pharmaceutical industry, as the sales volume of an infringing new drug or wonder drug may reach as high as hundreds of millions RMB, and the plaintiff's loss is far from fairly compensated even with a damage reward of RMB five million, which is the upper limit of statutory damage. However, under the rules of spoliation of evidence, the burden of proof is partially allocated to the defendant, which should provide financial materials possessed to support its claims of low profits. This would make it much easier for patentees in the pharmaceutical industry to obtain due compensations and thus improve the market value of new drugs and wonder drugs.

e. Implied license is introduced for Standard Essential Patents, to echo the PRC Antitrust Law

Article 14 of the **Draft** puts it as a principle that the patentee shall not abuse the patent right to eliminate or restrict competition. Furthermore, Article 85 of the **Draft** stipulates that if a

patentee participating in the development of a national standard does not disclose its Standard Essential Patents ("**SEPs**") during the standard-making process, it should be deemed as having licensed the entity implementing said national standard to use its SEPs (with royalty).

We understand that these Articles are introduced under the background of previous SEP-related antitrust lawsuits in the wireless communication industry, and aim at preventing patentees' patent hold-up with the standards. Antitrust practice against licensing of SEPs is becoming a rising star in IP practices, and we can imagine that this amendment pertinent to implied licensing of SEPs will produce influence on all industries, more or less.

Compared with wireless communication industry, standards in pharmaceutical industry are in a relatively lower concentration, and it is more possible for different standards in a group to replace each other. In addition, the standards of different pharmaceutical companies for the same drug may not be completely the same with each other, which makes it possible to design around the SEPs in some circumstance. Also, if a patent becomes essential to a standard, the patentee will face strict restrictions in asserting it against infringers. Considering all the factors, it seems that standards may not be as valuable to pharmaceutical companies as they are to wireless communication companies, and it is suggested that pharmaceutical companies should take comprehensive consideration on whether to incorporate its patent into standards to make it an SEP.

Finally, it should be noted that the **Draft** as mentioned has not become effective and is still open to further modifications. However, since the amendments mentioned above will have significant influence on the pharmaceutical industry, we would like to recommend that pharmaceutical companies pay early attention and make timely adjustments to their patent strategy if needed, so as to respond to the changes in a more effective way.

Important Announcement

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