November 11, 2011

Delivered by email to: IP.Policy©.uspto.gov

United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Elizabeth Shaw

In Re: Request for Comments on Intellectual Property Enforcement in China, 76 Fed. Reg. 64075 *(Oct.* 17,2011)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is filing these comments in response to the United States Patent and Trademark Office's (USPTO's) above-referenced notice. PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $49.4 billion in 2010 in discovering and developing new medicines.

Research-based pharmaceutical companies depend in large part on reliably enforceable patent rights to provide an appropriate incentive for the significant investment of resources and time that is needed for pharmaceutical research and development. A patent system that fosters innovation includes the hallmarks of certainty, transparency, fairness, and consistency. After enactment of China's first patent law in 1984, the Chinese government has worked to improve the protection of patent rights in China and has made strides towards achieving these goals. As explained below, however, further improvements to the country's comparatively new patent system would provide an even greater level of certainty, transparency, fairness, and consistency.

Our comments below focus on four of the topics identified by the USPTO in the above-referenced notice: evidence collection and preservation, damages and injunctions, enforcement of court orders, and the option of administrative patent enforcement. We believe more steps could and should be taken to create an environment that fosters innovation in China, ultimately benefitting not only multinational research-based pharmaceutical companies beginning to invest in China but also China's own innovative pharmaceutical industry. Ultimately, the benefits would flow to the people of China, as new medicines become available.

I. Evidence Collection and Preservation

Currently, China has not yet implemented a comprehensive set of evidentiary rules. While the Chinese Civil Procedure Law contains limited evidentiary provisions, most of the current evidence standards were established in judicial interpretations issued by the Supreme People's Court (SPC). The absence of official evidentiary standards leads to considerable variation in approach from court to court, particularly with respect to determining the relevance, sufficiency, and weight of evidence. Accordingly, as a threshold matter, we recommend enactment of a nationally applicable and comprehensive Evidence Law that would provide the courts and patent owners with a consistent and transparent set of evidentiary rules for patent litigation. In the meantime, additional guidance from the SPC would be helpful.

A significant impediment to successful patent protection in China is the lack of simple, robust discovery procedures to govern evidence collection, preservation, and presentation. Without sufficient discovery procedures, patent owners do not have a meaningful opportunity to show infringement in the Chinese courts. While China's Civil Procedure Law technically authorizes the court to seek evidence, this provision is seldom used. Instead, plaintiffs must collect and submit their own evidence to meet their burden of proof, which can include evidence from private investigations, overseas litigation, prior administrative proceedings, or employees of the defendant. Chinese law also provides for "evidence preservation" through an essentially *ex parte* court order (often granted only if a bond is paid) to preserve evidence that may be lost or difficult to obtain later. Although the court order can in theory be very effective-the resulting evidence is admissible in court-this mechanism in practice is not particularly helpful because most courts require substantial evidence of ongoing or imminent infringement before issuing the order. Where the primary evidence that would make this showing is the very evidence sought, this requirement effectively renders the evidence preservation option moot. Moreover, defendants sometimes ignore evidence preservation orders because the penalty for non-compliance is trivial and because the enforcement agencies lack resources. Without robust discovery procedures, patent owners, and foreign patent owners in particular, cannot effectively enforce their patent rights in China.

A national evidence law could also resolve some of the evidentiary hurdles related to expert testimony and sample testing that patent owners encounter when pursuing cases in China. The issues in patent cases can be highly technical and complex, often requiring evidence such as expert testimony and analytical testing of potentially infringing products. Chinese courts generally will not accept the results of analytical testing of infringing products performed by foreign companies. Patent owners sometimes cannot have samples tested by a Chinese institute/company because no Chinese institute/company has the capacity to conduct the particular test or the Chinese institute/company which has the capacity refuses to conduct analytical testing. In these cases, the foreign patent owner is deprived of the analytical evidence necessary to establish infringement. In addition, Chinese courts do not always permit testimony from expert witnesses familiar with the technology. Ordinarily, expert witnesses are designated by the court (they are often from state-owned institutions). This has the

effect of precluding qualified experts from foreign countries. Moreover, in our members' experience, opinions from court-cfesignated witnesses are accepted by the court without substantial cross-examination.

Another challenge faced by patent owners pursuing patent cases within the Chinese patent enforcement system is the existence of special technical requirements relating to the presentation of evidence. Specifically, Chinese courts generally accept evidence only in its original form. Evidence obtained in foreign countries must be notarized by a notary in the foreign country and then legalized by the relevant Chinese embassy or consulate. Documentary evidence in a foreign language must be translated by a court-authorized translation company in China, and documentary evidence generally must be introduced by a live witness. These technical evidentiary requirements can be burdensome when coupled with the absence of standardized evidentiary rules and discovery procedures.

II. Obtaining Damages and Injunctions

To effectively foster innovation, a patent enforcement system must provide meaningful relief to patent owners in the event of infringement *and* adequately deter prospective infringers. The pharmaceutical industry has found it extremely difficult, however, to prevent the marketing of potentially infringing follow-on products in China. In addition, even if a court Ultimately makes a finding of patent infringement, damages in China are insufficient to compensate the patent owner's for its losses, let alone to deter infringement in the first instance.

Injunctive Relief

Patent owners are highly dependent on preliminary injunctive relief to prevent the serious financial harm that results from the marketing of infringing products. Although preliminary injunctions are theoretically available in China, our members' experience has been that they are rarely granted. There are several reasons for this. In order to obtain a preliminary injunction, a patent owner must prove both infringement and irreparable harm. As discussed above, however, evidentiary hurdles often make it difficult for a patent owner to make the threshold showing of infringement, which is a more rigorous standard than the U.S. requirement of showing a likelihood of success on the merits. In addition, China does not have published or precedential standards governing the requirements for proving irreparable harm. Finally, Chinese patent law requires the court to rule on a preliminary injunction within 48 hours (or 96 hours where an extension has been granted). This time frame is typically insufficient for a complex pharmaceutical patent infringement case. Indeed, the SPC has cautioned the lower courts against issuing preliminary injunctions in cases involving complicated technologies. We suggest that the patent law (or both the patent law and the civil procedure law) be revised to permit courts substantially more time to rule on preliminary injunctions in cases involving complex technologies. We also recommend a change in the standard for a preliminary injunction (Le., likelihood of success on the merits) and greater clarity around the irreparable harm showing.

Pharmaceutical patent owners in particular can experience irreparable harm if sales of an infringing follow-on product are permitted and marketplace reliance on the branded product erodes. A system well-designed to foster pharmaceutical innovation thus typically makes patent infringement litigation possible prior to follow-on market entry *and* includes a meaningful connection between generic marketing authorization and potential patent infringement. These, too, are suggested areas requiring attention in China.

In particular, although in theory pharmaceutical patent owners may bring patent infringement litigation against follow-on applicants prior to market entry, they do not always learn of pending applications that implicate their patents. Moreover, the courts usually require evidence of actual patent infringement (e.g., selling product to a distributor or providing infringing active pharmaceutical ingredient to a foreign customer), so these cases are rarely brought. There is no artificial act of infringement (as there is in the U.S.) creating an automatic *right* to sue prior to market entry, simply because the follow-on applicant asserts non-infringement. This may be accomplished under current Chinese law via an interpretation of the Chinese analog to the so-called "Bolar" provision of 35 U.S.C. 271(e)(1) to indicate that the generation of data for submission to the regulatory agency for approval of a generic product is not an infringement of the patent, but seeking approval for marketing is infringement of the patent. We suggest a clear statutory right to bring suit prior to market entry once the follow-on applicant asserts non-infringement, and we further recommend discussion with stakeholders about an appropriate mechanism for notification of patent owners that applications for potentially infringing products are pending with the State Food and Drug Administration (SFDA).

Another issue stems from the lack of a robust connection between follow-on generic marketing authorization and potential patent infringement. Under current law in China, a follow-on applicant must identify relevant and unexpired patents in its application. There is, however, no mechanism to ensure the accuracy of the claims made. Further, if the applicant asserts that a patent exists but is not infringed, SFDA has the discretion to review and approve the application immediately, which has the effect of permitting the marketing of a potentially infringing product. As we have already noted, preliminary injunctions against infringement are rarely granted. Once approval has been granted, SFDA will rescind the approval only if there is a final court decision of patent infringement, which can take years. Yet, as we point out above, damages for infringement in the intervening years are likely to be insufficient. For this reason, we believe some thought should be given to a mechanism for identifying the patents that must be addressed by follow-on applicants, and we further recommend a regulatory complement to the injunctive relief available in court (for example, a stay on marketing authorization while the patent issue is worked out).

Damages

A robust patent enforcement system provides patent owners with meaningful compensation for financial losses due to infringement and deters infringers. These features give research-based companies the confidence they need to invest in developing new technologies and new medicines. In our members' experience, however, damages for patent infringement in China are difficult to obtain, and when obtained, do not sufficiently compensate patent owners for their financial losses (let alone deter infringement).

The Patent Law in China in theory permits four methods of damages calculation. In practice, the courts in Virtually every pharmaceutical patent case revert to the fourth method, which has a cap of roughly $156,000. The first method calculates actual losses suffered by the patent owner; the second method calculates the profits earned by the defendant from the infringing activities; and the third method calculates a "reasonable" licensing fee (sometimes multiplied threefold). In our experience, largely because of the evidentiary hurdles discussed above, patent owners - and foreign patent owners in particular - are typically unable to satisfy the evidentiary burden necessary to receive damages under one of these three methods. When the patent owner cannot establish damages using one of these three methods, it must resort to the fourth method: damages determined by the court (based on considerations like the patent type, and the conduct and circumstances of the infringement) but capped in every case at 1M RMB (about $156,000).

Addressing the evidentiary issues described in section I of these comments would substantially alleviate the damages problem, although we also believe that damages calculated via the fourth method should not be capped at 1M RMB. Additional theories - such as enhanced damages for willful infringement and attomey fees in some cases - would enhance the deterrent effect of the patent enforcement scheme and (in the case of attorney's fees) more appropriately compensate injured intellectual property owners. The U.S. system permits both such awards, and various European continental systems (including the German system) award attorney's fees to the prevailing party.

III. The Enforceability of Court Orders

In China, enforcement of most court orders - including orders for damages and injunctions - is not automatic. Instead, if the losing party fails to comply, the winning party must apply separately to an enforcement tribunal to compel enforcement. Enforcement tribunals have considerable discretion with respect to whether, and how firmly, to enforce an order. While in theory an individual or responsible party (of an enterprise) can be fined or jailed for violating a court order, the fine is trivial, and a jail sentence is rarely imposed. We therefore suggest amendments to the Civil Procedure Law that significantly increase the fine for contempt of court orders *and* provide the imposition of both the fine and a jail sentence at the same time.

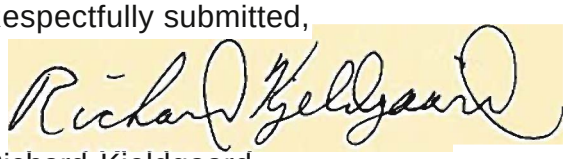
IV. Administrative Patent Enforcement

Patent owners have an altemative in China to patent infringement litigation: administrative patent enforcement. Specifically, a patent owner may obtain an administrative injunction against infringement from a local intellectual property authority, known as the Local Patent Administrative Bureau, or PAB. Local intellectual property authorities are hesitant to adjudicate patent infringement complaints, at least where the matter is complex, because they lack expertise and resources for these cases. They tend to encourage settlement unless the patent infringement is clear. Moreover, they are limited to injunctive remedies: they cannot award damages. Finally, they cannot impose sanctions if the infringer ignores the injunction. The patent owner in this case must apply to a court for enforcement of the administrative order. For these reasons, the administrative patent enforcement alternative in China is not structured as a meaningful option for pharmaceutical patent owners.

* * *

The USPTO states in its notice that ensuring the Chinese intellectual property system works in a "fair and timely manner for U.S. innovators" is a "top priority" for the U.S. government. PhRMA strongly endorses the USPTO's efforts to craft recommendations for improving the Chinese patent enforcement system and appreciates the opportunity to provide its views on that system. We would be delighted to provide further assistance to the USPTO and collaborating entities like IPEC, as the government moves forward with this initiative.

Respectfully submitted,



Richard Kjeldgaard
Deputy Vice President,
International Intellectual Property