



**By Electronic Submission**

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Office of Policy and External Affairs  
United States Patent and Trademark Office  
Alexandria, VA 22313-1450

**Re: Request for Comments on Intellectual Property Enforcement in  
China**

**Attn: Elizabeth Shaw**

Dear Ms. Shaw,

Interpat, an association of multinational research companies from the US, Europe, and Japan, is pleased to offer its comments on enforcement of patents in China. Many of our member companies have provided their individual comments in various fora. The present document is meant to offer general principles and concerns as opposed to individual cases.

Research based pharmaceutical companies are dependent upon predictable patent rights to provide the appropriate incentives for the significant investments needed for pharmaceutical research. These patents need to be enforced via a regime that is transparent and fair. Unfortunately, the experience of the research based pharmaceutical industry in China to date is that the level of certainty, transparency, or fairness has not provided the appropriate incentives for investment. Thus, we appreciate the opportunity to provide some suggestions on how to improve China's system of enforcement.

Based on these principles, we would like to comment on three of the five topics suggested in the Federal Register notice:

1. Evidence collection and preservation in Chinese courts,

2. Obtaining damages and injunctions, and
3. Enforceability of court orders.

### **Evidence collection and preservation in Chinese courts**

Any judicial system is dependent on consideration of all the relevant evidence. And, China has procedures in place for the preservation of evidence prior to trial. However, litigants have experienced differing results depending on the venue in China. Defendants in litigation sometimes do not comply with the court's requests, and it is difficult to obtain compliance with orders.

The requirements for legalization, notarization and document translation of evidence produced for litigation in China greatly hinders IPR protection for foreign companies in China. Foreign company Plaintiffs/patentees are often not able to get evidence into consideration due to technicalities and the need to use live witnesses to introduce the evidence.

Analytical results (such as XPRD) of infringing products conducted by foreign agencies are not accepted by Chinese courts. Thus, when all Chinese agencies that can provide such analytical services refuse to test the samples submitted by the foreign based patentee, the patentee has no means for obtaining analytical evidence showing infringement.

Generally, in patent infringement cases, the burden is on the patentee to prove infringement. However, China does not have discovery procedures. In some cases, after an initial showing is made, Chinese law does provide means for the preservation of evidence held by the defendant. However, the initial obstacles to providing preliminary evidence in order to obtain court orders to compel evidence or to preserve evidence are often prohibitory. Even when a court issues orders to compel or preserve evidence, the order can be ignored by defendants.

Patent infringement and invalidation hearings often involve complex technology, but only government or court-sanctioned experts can provide "expert testimony" and they are often not familiar with the technology. There needs to be greater opportunity for litigants to bring in testimony by independent experts and/or scientists.

When any of the above views regarding evidentiary difficulties in China has been communicated to SIPO or Chinese Courts at many occasions, the answer has been that the evidentiary rules are dictated by the relevant Chinese Civil Law and thus neither SIPO nor Courts have the authority to change this.

**Recommendation:** Since China is in the process of amending its Civil Procedure Law, we suggest that amendments to the relevant Chinese Civil Procedure Law be made to simplify the introduction of documentary evidence and to permit more testimonial evidence from all relevant persons, and for the court to have the means to compel evidence preservation where a party is uncooperative.

### **Obtaining damages and injunctions**

#### **Preliminary Injunctions to stop infringement:**

In many technologies, the ability to obtain a preliminary injunction is extremely important, since the sale of an infringing product can cause irreparable harm to the patentee. This is particularly true in the pharmaceutical industry, where the approval of a generic product severely impacts the marketplace expectations. However, preliminary injunctions have rarely issued in pharmaceutical patent cases in China. This is due in part to the fact that the Supreme Peoples' Court (SPC) in China has cautioned lower courts against issuing preliminary injunctions (PIs) for 'complicated' technologies. Preliminary injunctions issue fairly frequently for trademark and counterfeiting cases. We understand that a high percentage of petitions for preliminary injunction that are accepted by the courts are granted. However, many, if not most, such petitions in patent cases are simply not accepted by the courts, and thus the injunction is not granted, but this is not reflected in the statistics. We understand that the reason they are not accepted is that patent cases are often too complex for the court to rule on an injunction case in 48 hours as is required by existing law.

This often leads courts to simply decline to accept such motions, since the time is too short to properly rule on the injunction request due to the complexity of patent cases. One possible solution would be to allow the courts a longer period to decide the request. We understand that a request could be made to provide a longer period to rule on the request. Thus, lengthening the period for ruling on the preliminary injunction request would be preferable than simply not ruling on the petition. This would provide the courts the time needed to properly rule on the petition.

Another difficulty has been the need to establish infringement in seeking preliminary injunction (patent law article 66), a much higher standard than the U.S. standard "likelihood of success". Patentees also have had trouble proving "irreparable harm."

**Recommendation:** China should provide an additional track for preliminary

injunctions that allows the court a longer period of time to decide on petitions for preliminary injunctions, e.g., perhaps two or three weeks rather than 48 hours. This can be done by amending the Civil Procedure Law. And because the “irreparable harm” standard could lead to unintended outcome of a court-sanctioned infringement, China should consider adopting the more generally applied standard of “likelihood of success” for preliminary injunctions.

**Damages:**

The standard to prove damage to plaintiff, or benefit to defendant is high. When this is coupled with the difficulty in collecting evidence, many patentees have had to opt for the statutory damages provided by the Chinese patent law, which is between 10,000 RMB to 1,000,000 RMB.

**Recommendation:** China should lower standard of proof for damages; and increase the amount of statutory damages for patent infringement.

**Patent Linkage:** Further, while it is possible that 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 United States) 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 Bolar provision 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 an in infringement of the patent.

Another way to accomplish this goal is for China to adopt a patent linkage system where the regulatory agency withholds approval of a generic product pending resolution of patent issues. 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 or that the patent holder is notified of the application. 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.

And, as noted, preliminary injunctions against infringement are rarely granted. Finally, 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. And, as noted, 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).

**Recommendation:** 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). This could also be accomplished via judicial interpretation of the current Bolar provision to allow for patent litigation in the case of any activities going beyond the generation of data for submission to the SFDA.

#### **Enforceability of court orders**

China's Civil Procedure law provides that an individual or responsible party of an enterprise in contempt of a court order can be fined or jailed. In reality, such provision is not effective in deterring contempt of court orders such as order to preserve evidence. Further it is also often difficult to prove that the party has violated the court order.

**Recommendation:** China should consider amending the relevant civil procedure law to set a high amount for a minimum fine and other sanctions for a party in contempt of a court order.

#### **Invalidation actions at the Patent Reexamination Board (PRB) within the State Intellectual Property Office (SIPO).**

As is the case with many countries, patent validity challenges are handled within the patent office. However, the threshold for initiating such actions is low, and there is little if any application of *res judicata* principles to eliminate retrying issues handled during patent prosecution or prior invalidation actions. As a result, patentees are often faced with multiple invalidation actions on the same patent. And, it is quite common for challengers who have lost an action to simply file a new one on very similar grounds.

**Recommendation:** SIPO should set forth rules applying principles of estoppel and *res judicata* to invalidation actions.

**Important note:** China is amending its Civil Procedure Law currently and China's National People's Congress is soliciting comments from the public. The notice is posted today Oct 31, 2011 and the deadline for providing

comments is Nov 30, 2011. <http://npc.people.com.cn/GB/16072244.html>

Respectfully Submitted,

Lawrence T. Welch

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