



**By Electronic Submission**

**Ip.policy@uspto.gov**

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,

I am writing on behalf of the Biotechnology Industry Organization (BIO) in response to the *Request for Comments on Intellectual Property Enforcement in China*. BIO is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. States and 32 countries around the world. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics.

The majority of BIO's members are small and medium sized enterprises that currently do not have products on the market. As such BIO's members rely heavily on the strength and scope of their patents to generate investment to take their technologies to commercialization. More and more, BIO's members are looking abroad as they expand their markets and R&D and commercialization efforts.

China, in particular, is viewed by BIO as a key emerging market. Many of BIO's more established companies already do business in China, and over recent years several of BIO's small and medium sized members have also expressed an interest in doing business there. Its recently announced 12th 5-Year Plan provides considerable support for biotechnology innovation and aims to support both the development and manufacture of new biotechnology products. This 5-year plan holds substantial promise to elevate China's position and leadership in the industry.

Earlier this year, BIO hosted a mission to Beijing and Shanghai where 13 CEOs of small and medium sized biotechnology companies met with key research parks and government officials. Furthermore, in October BIO hosted its first ever BIO China event which attracted over 700 biotechnology professionals from China and other parts of Asia along with professionals from US and Europe.

Accordingly, legislation and regulation that have the potential to impact the biotechnology sector are of great importance to BIO. The importance of intellectual property protection is now understood in China. However, it appears as though the IP laws are implemented and enforced in ways that benefit Chinese companies over foreign companies. If China aims to be a leader in biotechnology it needs to understand that intellectual property protections are fundamental for creating an enabling environment for biotechnology. In this regard, China has yet far to go.

### **Courts Rules are Insufficient to Enforce Patent Rights**

Because of the significant investment that is required to bring a biotechnology product to market--often hundreds of millions of dollars-- one of the most critical aspects of patent enforcement rights is injunctive relief. In this regard, Chinese law has an ineffective preliminary injunction mechanism as it fails to stop the filing and authorization of a generic product. Biotechnology companies are advised by Chinese law firms that the company must wait until the product is actually sold in China before a patent holder can bring an infringement action. This is because the Supreme Peoples' Court has cautioned lower courts from issuing preliminary injunctions for 'complicated' technologies and the rules for preliminary injunctions require a decision in a 48 hour window. As a result, judges often refuse to entertain preliminary injunction motions because they are unable to reach a decision on the motion within the prescribed time limit. Thus, biotechnology companies cannot obtain an injunction until the conclusion of the infringement suit. Additionally, success in an infringement action does not limit the State Food and Drug Administration (SFDA) from approving other generic applications.

One critical deterrent for patent infringement is the damages that an infringer must pay upon a finding of infringement. In China, our members have found statutory compensation insufficient for infringement of U.S. patents. This, in conjunction with the inability to obtain a preliminary injunction results in significant costs to the U.S. innovator and minimal loss to the infringer of Chinese patent law. Statutory compensation for infringement should be towards the statutory ceiling of RMB 1,000,000 and should also include a punitive damages provision (e.g. treble damages).

Finally, our members also report problems with the notarization requirement, discovery procedures, and compliance with court orders in infringement suits. Notarization requirements are cumbersome and provide notice far too early for the

potential defendant. China also has prohibitive discovery procedures which greatly hinders U.S. patent holders to bring infringement actions. Even when U.S. patent holders are successful, they often report that court orders are routinely ignored by defendants and the defendants pay little to no consequences for disobeying a court order. Finally, China restricts expert testimony to government or court-sanctioned experts. These ‘experts’ are not familiar with the technology and cannot adequately testify in an infringement action.

### **China Patent Enforcement does not Effectively Address the Exportation of Infringing Products**

The Chinese government contends that exportation of illegally manufactured infringing products does not violate U.S. company patent rights in China. These products are not subject to SFDA oversight or regulatory review. As a result, the quality and quantity of the exported drugs and API is indeterminable. Additionally, Chinese law does not allow for a preliminary injunction to stop the export of these infringing products. Chinese law requires a sale in China (and not an export sale) in order to infringe a patent. Chinese customs procedures require identification of the exporter and successful enforcement of patent rights in Chinese court; which as mentioned before is impossible without a sale in China. Chinese generic manufacturers take advantage of this loop-hole by only exporting their products outside the country. However, even in cases where a generic manufacturer sells their product in China and abroad, damages are calculated only on lost profits in China (not abroad) which does not adequately redress the violation of Chinese patent law.

### **Chinese Agencies Undermine U.S. Patent Rights in China**

China’s patent enforcement involves government efforts to undermine U.S. patent rights in China. As an example, the National Program for the Development of Major Drugs is a government sponsored program which funds the manufacture of generic versions of U.S. patented pharmaceuticals. The Ministry of Health and the State Food and Drug Administration (SFDA) both are stakeholders in this program. Moreover, the SFDA also will not recognize U.S. patent rights through mechanisms such as patent linkage. The SFDA claims no responsibility for enforcing patents and reviews generic filings without considering whether or not those granting authorization would induce generics to violate Chinese patent law.

### **Compulsory Licensing Threats**

While a few people complain that compulsory licensing is not used enough, our biotechnology companies report that they are consistently threatened with compulsory licenses in pricing negotiations.

In conclusion, BIO appreciates the opportunity to provide comments regarding patent enforcement in China and we agree generally with the recommendations made by all industry sectors as reflected in the attached document.

Sincerely,

A handwritten signature in black ink, appearing to read "Lila Feisee". The signature is written in a cursive style with a large, looping flourish at the top.

Lila Feisee  
Vice President of Global Intellectual Property Policy  
Biotechnology Industry Organization

Joseph Damond  
Senior Vice President for International Affairs  
Biotechnology Industry Organization

## PATENT ENFORCEMENT IN CHINA

### Summary of Industry Views

<b>Topic</b>	<b>Industry Observation</b>	<b>Industry Recommendation</b>
1. Utility Model Patents	1. Chinese companies obtain utility model (UM) patents that merely copy existing technology in the public domain, then assert the UM patents against foreign companies or use these patents to defend themselves in suits against the true inventor. <sup>[1,6]</sup>	1. China's State Intellectual Property Office (SIPO) should enhance patent quality and step up the fight against low quality patents. <sup>[2,3]</sup> 2. SIPO should create an opposition proceeding specifically for UM patents. <sup>[3]</sup> 3. SIPO and/or Chinese courts should penalize applicants who submit UM filings in bad faith (i.e., knowingly copying another's invention). <sup>[3]</sup> 4. China should cancel the subsidy policy that incentivizes excessive UM filings in the first place. <sup>[3]</sup>
	2. U.S. and other foreign inventors almost completely ignore UM patents, in part because they are less familiar with them than invention patents. <sup>[1]</sup>	5. U.S. Government (USG) should increase training/outreach to U.S. companies to increase their awareness of UM patents as an option in their patent acquisition strategy. <sup>[4]</sup>
	3. Although it is possible to simultaneously file both types of applications in China and thus obtain UM protection while the invention application is being examined, this strategy is apparently not available if the application enters China via the Patent Cooperation Treaty (PCT), disadvantaging foreign companies that rely on PCT. <sup>[3]</sup>	6. SIPO should allow applicants to apply for both a UM and invention patent under the PCT, with the understanding that the UM patent will be abandoned once SIPO grants the invention patent. <sup>[3]</sup>

Topic	Industry Observation	Industry Recommendation
<p>2. Judicial Impartiality</p>	<p>1. Some Chinese judges display local protectionism in favor of local defendants (including foreign companies with local manufacturing presence), which is due, in part, to a lack of judicial independence from political interference.<sup>[1,5,8]</sup></p>	<p>1. China should reform the Judges Law of 1995 to modernize and strengthen the authority and independence of the judiciary.<sup>[6]</sup></p> <p>2. China should legislate and enforce stricter penalties on any judge engaging in (1) ex parte communication regarding the merits of the case without knowledge of all parties or (2) any discussions regarding the merits of the case with judges outside the judicial panel handling the case.<sup>[4, 6]</sup></p> <p>3. China should impose and/or enforce serious penalties for any party offering bribes to judges and for the judge receiving a bribe.<sup>[6]</sup></p> <p>4. China should increase enforcement by Procuratorate or internal affairs department of ethical violations.<sup>[4]</sup></p> <p>5. USG should promote capacity building for judges on international norms of judicial conduct.<sup>[4,5,6]</sup></p>
	<p>2. Some Chinese judges engage in ex parte communication with one side, or confer about the case with the appellate court prior to issuing a ruling.<sup>[6]</sup></p>	<p>6. China should legislate and enforce stricter penalties on any judge engaging in (1) ex parte communication regarding the merits of the case without knowledge of all parties or (2) any discussions regarding the merits of the case with judges outside the judicial panel handling the case.<sup>[4,6]</sup></p> <p>7. China should impose and/or enforce serious penalties for any party offering bribes to judges and for the judge receiving a bribe.<sup>[6]</sup></p> <p>8. China should increase enforcement by Procuratorate or internal affairs department of ethical violations.<sup>[4]</sup></p> <p>9. USG should promote capacity building for judges on international norms of judicial conduct.<sup>[4,5,6]</sup></p>
	<p>3. Some Chinese judges merely copy and paste a party's arguments into the final decision.<sup>[7]</sup></p>	<p>10. China should legislate and enforce stricter penalties on any judge engaging in ex parte communication regarding the merits of the case without knowledge of all parties.<sup>[4,6]</sup></p> <p>11. USG should train judges on international norms of judicial conduct.<sup>[4,5,6]</sup></p>

Topic	Industry Observation	Industry Recommendation
3. Case Acceptance	1. When a complaint is filed, Chinese courts first decide whether to “accept” the case, applying unclear and inconsistent standards. <sup>[4,7,8]</sup>	1. China should publish a binding judicial interpretation clearly explaining what information/evidence a plaintiff must submit in order for a patent infringement case to be accepted. <sup>[8]</sup>
	2. Decisions refusing to accept a case are not appealable. <sup>[4,8]</sup>	2. China should permit appeals of decisions refusing to accept a case, similar to appeals of case dismissals in US courts. <sup>[4,8]</sup>
	3. Judges have notified parties of the case acceptance decision over the phone, not in writing. <sup>[7,8]</sup>	3. China’s courts should publish, in writing, all decisions accepting or denying the case, with articulated reasoning if a case is not being accepted. <sup>[7,8]</sup>
4. Publishing Decisions	1. Courts selectively publish their decisions because they do not want to be bound to them in future cases. <sup>[7,8]</sup>	1. China’s courts should publish all decisions online. <sup>[7,8,9]</sup>
5. Evidence Collection and Preservation	1. China has no robust system for evidentiary discovery; thus litigants cannot require the other side to produce evidence in its possession which is needed to prove infringement or even to have a case accepted. <sup>[1,8]</sup>	1. China should promulgate a law of evidence, which presently does not exist and is only partly covered by certain Supreme Courts rules and a few rules in the Code of Civil Procedures. <sup>[6]</sup> 2. Chinese courts should relax the burden of evidence required of right holders in pursuing infringers. <sup>[9]</sup> 3. Chinese courts should impose sanctions, including criminal liability and adverse evidentiary presumptions, on parties that fail to comply with discovery orders. <sup>[4,8]</sup>
	2. To obtain an order for evidence preservation, the requesting party must meet a high threshold that is both unclear and inconsistently applied. <sup>[3,9]</sup>	4. China should publish a binding judicial interpretation clearly explaining what information/evidence a plaintiff must submit when requesting evidence preservation. <sup>[8]</sup> 5. Chinese courts should relax the burden of evidence required of right holders in requesting evidence preservation. <sup>[9]</sup>
	3. Where evidence seizure is ordered, judges actually go out and seize the evidence themselves, which is a waste of the judges’ time. <sup>[4,6]</sup>	6. Bailiffs should undertake the collection of evidence under the judges’ direction, and such work should not be done by the judges themselves. <sup>[4,6]</sup>

Topic	Industry Observation	Industry Recommendation
6. Notarization of Evidence	1. All evidence obtained abroad must be notarized in the home country and then forwarded to the Chinese embassy in the home country for legalization, imposing significant cost and delay on foreign patent litigants. <sup>[1,2,3,4,7,8]</sup>	<ol style="list-style-type: none"> <li>China should delete the requirement for the powers of attorney given to Chinese lawyers or agents to be in notarized-, or notarized- and legalized-, form.<sup>[2]</sup></li> <li>China should replace the systematic notarization and legalization of documents by an optional decision to be made by the court on a case-by-case basis, where there is reasonable doubt regarding the authenticity and/or content of a document.<sup>[2]</sup></li> <li>China should delete the notarization and/or legalization requirements from administrative practice.<sup>[2]</sup></li> <li>China should join the “Hague Convention of 5 October 1961 Abolishing the Requirement of Legalisation for Foreign Public Documents” (“public documents” include patents, copyright registration certificates, and court rulings).<sup>[7,8]</sup></li> </ol>
7. Protective Orders	1. There is no mechanism to ensure that confidential business information, submitted under seal during litigation, remains protected from public disclosure or misappropriation. <sup>[8]</sup>	<ol style="list-style-type: none"> <li>Impose sanctions, including criminal liability, on parties that fail to comply with court orders.<sup>[4,8]</sup></li> <li>Direct that bailiffs enforce court orders, including seizure and freezing of assets.<sup>[4,6]</sup></li> </ol>
8. Expert Witnesses	1. Courts often require the use of government-sanctioned witnesses, with no mechanism to impeach, question or cross-examine these witnesses, or to introduce one’s own expert. <sup>[4,8]</sup>	<ol style="list-style-type: none"> <li>Chinese courts should allow parties to bring their own experts, with full opportunity for cross-examination, and then decide the case based on these opposing views.<sup>[4,8]</sup></li> <li>China should clarify the roles, qualifications, and operating procedures for courts’ use of experts.<sup>[5,8]</sup></li> </ol>
	2. Courts elevate documentary evidence over live testimony, without a principled reason. <sup>[8]</sup>	<ol style="list-style-type: none"> <li>China should promulgate a law of evidence, which presently does not exist and is only partly covered by certain Supreme Courts rules and a few rules in the Code of Civil Procedures.<sup>[6]</sup></li> <li>China should clarify the roles, qualifications, and operating procedures for courts’ use of experts.<sup>[5,8]</sup></li> </ol>
9. Damages	1. Damages awards are low (median \$7,500 in civil IP actions brought by foreigners from 2006-09). <sup>[1,8,9]</sup>	1. China should award larger damages, including punitive damage awards, for IP-related court judgments as a stronger deterrent to IP infringers. Increase statutory compensation of RMB 500,000 (US \$73,206) to accommodate new situations. <sup>[9]</sup>
	2. Proving damages is difficult, given the inability to collect evidence absent discovery. <sup>[1,3]</sup>	See Evidence Collection and Preservation.

<b>Topic</b>	<b>Industry Observation</b>	<b>Industry Recommendation</b>
10. Injunctions	1. Courts have denied requests for injunction where the patent was deemed essential to the local economy. <sup>[2]</sup>	1. Clarify under what circumstances a patentee loses his right to claim injunctive relief. <sup>[2]</sup>
11. Enforceability of Court Orders	1. Chinese courts lack the power to hold uncooperative defendants in contempt or, where such power exists, they refuse to exercise it. <sup>[1,3,7]</sup>	1. Impose sanctions, including criminal liability and adverse evidentiary presumptions, on parties that fail to comply with court orders. <sup>[4,8]</sup> 2. Direct that bailiffs enforce court orders, including seizure and freezing of assets. <sup>[4,6]</sup>
	2. It is very difficult to collect damages or enforce an injunction against a company that relocates to a different province or reincorporates as a new entity. <sup>[1,3,8]</sup>	3. The court's order should attach to, and run with, the defendant company's executives and any privies of the company. <sup>[8]</sup>
12. Administrative Enforcement	1. Administrative officials have limited investigatory powers. <sup>[1]</sup> Specifically, although the Patent Administrative Enforcement Rules (effective Feb. 1, 2011) give the local intellectual property offices (IPOs) the authority to collect evidence, IPOs lacks authority to compel evidence production; thus a suspected infringer can refuse to comply with an IPO's investigation. <sup>[10]</sup>	1. IPOs should be staffed by professionally trained personnel with the power of enforcement. <sup>[6]</sup> 2. China should publish all IP-related administrative cases online. <sup>[9]</sup> 3. USG should lend more technical assistance to relevant IPOs and engage in cooperative investigations. <sup>[9]</sup> 4. China should promote more dialogue between provincial and local IPOs to share experiences and best practices, in an effort to achieve more consistent enforcement across regions and jurisdictions. <sup>[5]</sup> 5. China should increase funding and resources for local administrative agencies that investigate infringement. <sup>[5]</sup> 6. China should delete the notarization and/or legalization requirements from administrative practice. <sup>[2]</sup>

<sup>1</sup> U.S. International Trade Commission, China: Intellectual Property Infringement, Indigenous Innovation Policies, and Frameworks for Measuring the Effects on the U.S. Economy, Inv. No. 332-514 (Dec. 13, 2010), <http://www.usitc.gov/publications/332/pub4199.pdf>.

<sup>2</sup> European Business in China Position Paper 2010/2011, [http://www.eurochamber.com.cn/images/documents/marketing\\_department/beijing/publications/2010/intellectual\\_property](http://www.eurochamber.com.cn/images/documents/marketing_department/beijing/publications/2010/intellectual_property)

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[rights.pdf](#)); European Business in China Position Paper 2009/2010, [http://www.europeanchamber.com.cn/images/documents/pp\\_2009-2010/intellectual\\_property\\_rights\\_en.pdf](http://www.europeanchamber.com.cn/images/documents/pp_2009-2010/intellectual_property_rights_en.pdf); European Business in China Position Paper 2008/2009, [http://www.europeanchamber.com.cn/images/documents/marketing\\_department/beijing/publications/2008/pp2008/intellectual\\_property\\_rights.pdf](http://www.europeanchamber.com.cn/images/documents/marketing_department/beijing/publications/2008/pp2008/intellectual_property_rights.pdf).

<sup>3</sup> Industry Roundtable, Shanghai, July 29, 2011.

<sup>4</sup> Industry Roundtable, Guangzhou, Aug. 1, 2011.

<sup>5</sup> U.S.-China Business Council, *2011 Special 301 Review* (Feb. 15, 2011), [http://www.uschina.org/public/documents/2011/ustr\\_special\\_301\\_review.pdf](http://www.uschina.org/public/documents/2011/ustr_special_301_review.pdf).

<sup>6</sup> American Chamber of Commerce in South China, *2011 "White Paper" on the Business Environment in China*, <http://www.amcham-southchina.org/uploadFiles/2011%20white%20paper.zip>; American Chamber of Commerce in South China, *2010 "White Paper" on the Business Environment in China*, <http://www.amcham-southchina.org/uploadFiles/2010%20White%20Paper.zip>.

<sup>7</sup> Industry Roundtable, Beijing, July 26, 2011.

<sup>8</sup> Industry Roundtable, Washington, DC, July 19, 2011.

<sup>9</sup> American Chamber of Commerce in the People's Republic of China, *2010 White Paper on the State of American Business in China*, <http://web.resource.amchamchina.org/news/WP2010LR.pdf>.

<sup>10</sup> Maarten Roos, *China Strengthens Administrative Enforcement of Patent Infringements* (March 3, 2011), <http://www.rplawyers.com/lwfbxqe.asp?id=135>.