



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

Topic	Industry Observation	Industry Recommendation
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. ^[1,6]	1. China's State Intellectual Property Office (SIPO) should enhance patent quality and step up the fight against low quality patents. ^[2,3] 2. SIPO should create an opposition proceeding specifically for UM patents. ^[3] 3. SIPO and/or Chinese courts should penalize applicants who submit UM filings in bad faith (i.e., knowingly copying another's invention). ^[3] 4. China should cancel the subsidy policy that incentivizes excessive UM filings in the first place. ^[3]
	2. U.S. and other foreign inventors almost completely ignore UM patents, in part because they are less familiar with them than invention patents. ^[1]	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. ^[4]
	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. ^[3]	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. ^[3]

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.^[1,5,8]</p>	<p>1. China should reform the Judges Law of 1995 to modernize and strengthen the authority and independence of the judiciary.^[6]</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.^[4, 6]</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.^[6]</p> <p>4. China should increase enforcement by Procuratorate or internal affairs department of ethical violations.^[4]</p> <p>5. USG should promote capacity building for judges on international norms of judicial conduct.^[4,5,6]</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.^[6]</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.^[4,6]</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.^[6]</p> <p>8. China should increase enforcement by Procuratorate or internal affairs department of ethical violations.^[4]</p> <p>9. USG should promote capacity building for judges on international norms of judicial conduct.^[4,5,6]</p>
	<p>3. Some Chinese judges merely copy and paste a party's arguments into the final decision.^[7]</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.^[4,6]</p> <p>11. USG should train judges on international norms of judicial conduct.^[4,5,6]</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. ^[4,7,8]	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. ^[8]
	2. Decisions refusing to accept a case are not appealable. ^[4,8]	2. China should permit appeals of decisions refusing to accept a case, similar to appeals of case dismissals in US courts. ^[4,8]
	3. Judges have notified parties of the case acceptance decision over the phone, not in writing. ^[7,8]	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. ^[7,8]
4. Publishing Decisions	1. Courts selectively publish their decisions because they do not want to be bound to them in future cases. ^[7,8]	1. China’s courts should publish all decisions online. ^[7,8,9]
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. ^[1,8]	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. ^[6] 2. Chinese courts should relax the burden of evidence required of right holders in pursuing infringers. ^[9] 3. Chinese courts should impose sanctions, including criminal liability and adverse evidentiary presumptions, on parties that fail to comply with discovery orders. ^[4,8]
	2. To obtain an order for evidence preservation, the requesting party must meet a high threshold that is both unclear and inconsistently applied. ^[3,9]	4. China should publish a binding judicial interpretation clearly explaining what information/evidence a plaintiff must submit when requesting evidence preservation. ^[8] 5. Chinese courts should relax the burden of evidence required of right holders in requesting evidence preservation. ^[9]
	3. Where evidence seizure is ordered, judges actually go out and seize the evidence themselves, which is a waste of the judges’ time. ^[4,6]	6. Bailiffs should undertake the collection of evidence under the judges’ direction, and such work should not be done by the judges themselves. ^[4,6]

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. ^[1,2,3,4,7,8]	<ol style="list-style-type: none"> 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.^[2] 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.^[2] China should delete the notarization and/or legalization requirements from administrative practice.^[2] 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).^[7,8]
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. ^[8]	<ol style="list-style-type: none"> Impose sanctions, including criminal liability, on parties that fail to comply with court orders.^[4,8] Direct that bailiffs enforce court orders, including seizure and freezing of assets.^[4,6]
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. ^[4,8]	<ol style="list-style-type: none"> 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.^[4,8] China should clarify the roles, qualifications, and operating procedures for courts’ use of experts.^[5,8]
	2. Courts elevate documentary evidence over live testimony, without a principled reason. ^[8]	<ol style="list-style-type: none"> 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.^[6] China should clarify the roles, qualifications, and operating procedures for courts’ use of experts.^[5,8]
9. Damages	1. Damages awards are low (median \$7,500 in civil IP actions brought by foreigners from 2006-09). ^[1,8,9]	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. ^[9]
	2. Proving damages is difficult, given the inability to collect evidence absent discovery. ^[1,3]	See Evidence Collection and Preservation.

Topic	Industry Observation	Industry Recommendation
10. Injunctions	1. Courts have denied requests for injunction where the patent was deemed essential to the local economy. ^[2]	1. Clarify under what circumstances a patentee loses his right to claim injunctive relief. ^[2]
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. ^[1,3,7]	1. Impose sanctions, including criminal liability and adverse evidentiary presumptions, on parties that fail to comply with court orders. ^[4,8] 2. Direct that bailiffs enforce court orders, including seizure and freezing of assets. ^[4,6]
	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. ^[1,3,8]	3. The court's order should attach to, and run with, the defendant company's executives and any privies of the company. ^[8]
12. Administrative Enforcement	1. Administrative officials have limited investigatory powers. ^[1] 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. ^[10]	1. IPOs should be staffed by professionally trained personnel with the power of enforcement. ^[6] 2. China should publish all IP-related administrative cases online. ^[9] 3. USG should lend more technical assistance to relevant IPOs and engage in cooperative investigations. ^[9] 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. ^[5] 5. China should increase funding and resources for local administrative agencies that investigate infringement. ^[5] 6. China should delete the notarization and/or legalization requirements from administrative practice. ^[2]

¹ 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>.

² European Business in China Position Paper 2010/2011, http://www.eurochamber.com.cn/images/documents/marketing_department/beijing/publications/2010/intellectual_property

[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; 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.

³ Industry Roundtable, Shanghai, July 29, 2011.

⁴ Industry Roundtable, Guangzhou, Aug. 1, 2011.

⁵ U.S.-China Business Council, *2011 Special 301 Review* (Feb. 15, 2011), http://www.uschina.org/public/documents/2011/ustr_special_301_review.pdf.

⁶ 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>.

⁷ Industry Roundtable, Beijing, July 26, 2011.

⁸ Industry Roundtable, Washington, DC, July 19, 2011.

⁹ 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>.

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



Motor & Equipment Manufacturers Association

The Voice of the Motor Vehicle Supplier Industry

1030 15th Street, NW, Suite 500 East • Washington, DC 20005
202-393-6362 • Fax: 202-737-3742 • www.mema.org

November 4, 2011

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Department of Commerce
600 Dulany Street
Alexandria, VA 22314

**RE: Request for Comments on Intellectual Property Enforcement in China
[Docket No. PTO-C-2011-0056]**

Dear Mr. Kappos:

The Motor & Equipment Manufacturers Association (MEMA) represents over 700 companies that manufacture and remanufacture motor vehicle parts for use in the light- and heavy-duty vehicle original equipment and aftermarket industries. Motor vehicle parts manufacturers are the nation's largest manufacturing sector, directly employing over 685,000 American workers.¹

Introduction

Given the growing economic relations between the U.S. and China – the world's two largest economies – it is imperative that intellectual property (IP) enforcement in China meets a standard that allows American companies and American innovation to remain competitive. The motor vehicle parts supplier industry is responsible for nearly 40 percent of the U.S. automotive research and development and is responsible for two-thirds of the value of a new vehicle. Much of the intellectual capital required for the design, testing and engineering of new parts and systems for motor vehicles comes from suppliers.

China's growing domestic market will play a crucial role in our industry's future growth, but only if American companies have confidence that China's patent system is fair and efficient. China's role in the global economy demands such a system and the U.S. government must work with China, in the context of economic cooperation, to achieve this goal.

Acquisition and Enforcement of Utility Model and Design Patents

The ease of obtaining utility model and design patents can hurt foreign IP owners. Utility model and design patents are obtained in China with no substantive examination prior to the patents being granted. Additionally, these patents can be obtained in approximately 12 to 18 months, compared to the timeframe of about five years that it takes to receive a standard patent in China.

Foreign IP owners must adopt an aggressive and extensive China patenting model. Motor vehicle parts manufacturers have faced efforts by Chinese violators to register the foreign firm's inventions and designs in China, which gives the violator a market advantage. Though foreign IP owners can seek invalidation of these registrations through the China Patent Office, the timeframe to reach resolution of such cases takes six to 12 months, which provides the registrant a tactical advantage.

MEMA encourages the U.S. Patent and Trademark Office (U.S. PTO) to seek clarification that if copyright continues to subsist in a design or artistic work, that it is industrially applied. Chinese law is currently unclear on this point.

¹ MEMA represents its members through four affiliate associations: Automotive Aftermarket Suppliers Association (AASA); Heavy Duty Manufacturers Association (HDMA); Motor & Equipment Remanufacturers Association (MERA); and, Original Equipment Suppliers Association (OESA). Suppliers manufacture and remanufacture the parts and technology used in the domestic production of millions of new cars and trucks produced each year, as well as the aftermarket products necessary to repair and maintain vehicles on the road today.



Automotive Aftermarket
Suppliers Association



Heavy Duty
Manufacturers Association



Motor & Equipment
Remanufacturers Association



Original Equipment
Suppliers Association

Evidence Collection and Preservation in Chinese Courts

Evidence collection in China has become more difficult for IP owners. Infringers are using more secretive locations for infringing activities and retaining small amounts of product at these locations to minimize fines or damages resulting from raids.

Chinese courts have proved challenging for motor vehicle parts suppliers. The courts seem reluctant to accept evidence other than that which is notarized, which can be difficult to arrange. In addition, evidence submissions are often dismissed without reasoning other than being "unreliable." MEMA encourages the U.S. PTO to request that Chinese courts rely on clear standards and guidelines in making decisions.

Obtaining Damages and Injunctions

Though preliminary injunctions like preservation orders are possible in China, the courts often refuse to issue such orders favoring instead a full hearing in which the court reviews all relevant evidence. This lengthy and academic process is typical of Chinese courts and inhibits aggressive patent protection which often relies on quick court orders.

As a result, IP owners are forced to carry out raids through the Patent Bureaus to obtain quasi-preliminary injunctions followed by seeking damages and formal court-issued injunctions; a costly process for foreign IP owners. MEMA encourages the U.S. PTO to seek improvements in this process.

Enforceability of Court Orders

In many cases, infringers refuse to acknowledge court orders made against them unless visited by court bailiffs reminding them of the importance of complying with the orders. This is particularly problematic when damages have been awarded. The Chinese government must seek ways to elevate respect for their judiciary. Until the Chinese courts are respected, infringers will continue to ignore court awards and orders.

Administrative Patent Enforcement

China set up an extensive administrative patent enforcement system many years ago in response to high levels of IP violations. The experience with this system by motor vehicle parts manufacturers has been generally positive. The patent bureaus tend to act sensibly and quickly, and in the most serious cases, aggressively. One fault with Chinese patent enforcement is that it allows Chinese pirates to use the system against rightful patent owners. Patent bureaus must be able to make a preliminary determination as to the rightful ownership of the patent rights that they are asked to enforce. This would be particularly helpful with utility model patents and design patents, which can be obtained by anyone for old technology, designs, etc., without any substantive examination by the Chinese Patent Office.

Conclusion

MEMA supports efforts by the U.S. PTO and the other Federal agencies to better understand the challenges with China's patent enforcement system and urges the government to press China to make necessary improvements that allow for fair competition. For more information, please contact Dan Houton, MEMA Director of Government Relations at 202-312-9250 or dhouton@mema.org.

Sincerely,



Ann Wilson
Senior Vice President, Government Affairs

Hernandez, Jesus

From: Carl-Lorenz Mertesdorf <carl-lorenz_mertesdorf@huntsman.com>
Sent: Friday, November 04, 2011 12:15 PM
To: IP Policy
Cc: Ron D Brown
Subject: Request for Comments
Attachments: Huntsman vs Longshen.pdf

To

the United States Patent and Trademark Office, Department of Commerce

Dear Sir,

Pursuant to your Request for Comments on Intellectual Property Enforcement in China of October 17, 2011 published in the Federal Register / Vol. 76, No. 200 [Docket No. PTO-C-2011-0056], we wish to submit the attached document. The document summarizes our case along with our conclusion and recommendation for improving the system.

Yours sincerely

Carl-Lorenz Mertesdorf
Huntsman Advanced Materials (Switzerland) GmbH
Klybeckstrasse 200
4057 Basel, Switzerland
Tel.: +41 61 299 2263 (office); +41 79 788 64 86 (mobile)
Fax: +41 61 299 2512
e-mail: carl-lorenz_mertesdorf@huntsman.com

Request for Comments on Intellectual Property Enforcement in China

of

United States Patent and Trademark Office, Department of Commerce

Summary of the Case:

On September 29, 2007 Huntsman sued Colva (a subsidiary of Longshen) before Intermediate People's Court in Shanghai for infringement of Huntsman's Chinese textile dyestuff patent No. ZL00106403.7 (Case: (2007)沪一中民五(知)初字第 364 号 = (2007) Hu Yi Zhong Min Wu (Zhi) Chu Zi Di 364 Hao). Colva offers for sale and sells Colvazol Super Black LC-G and Colvazol Super Black LC-R.

In March 2008 the court appointed Shanghai Science and Technology Consulting Service Center (Service Center) to prepare an expert opinion on the technical issues underlying the case. The Service Center in turn appointed three individual experts to render the technical opinion on behalf of the Service Center. The senior expert is a former chief engineer of a local dyestuff company, whereas the two other experts are still employed by another local dyestuff company and a local dyestuff research institute. The appointment of the experts was challenged by plaintiff without success. Because the Service Center is not equipped to carry out chemical testing of defendant's products, it appointed the Shanghai Research Institute of Organic Chemistry of Chinese Academy of Science (SRIOC). SRIOC used advanced analytical techniques to analyze the defendant's dyestuff and issued their comprehensive testing report on February 5, 2010 which confirmed infringement.

The Service Center submitted the testing report to the Court, and the Court circulated copies to the parties for cross-examination. Plaintiff signed to confirm the receipt of the testing report on 10 February 2010 and submitted to the Court its cross-examination opinion on 12 March 2010. Defendant also signed to confirm the receipt of the testing report and submitted its cross-examination opinion around the similar time.

In August 2010, the Service Center informed plaintiff that the experts deem the testing report incomplete and that supplementary tests are required as result of discussion between SRIOC and the experts. However, SRIOC never confirmed that they deem supplementary tests necessary. In their written opinion dated January 10, 2011 the Service Center provided the experts' statement as to the SRIOC's testing report and the supplementary tests requested. The requested tests were described, but the expert's arguments were neither clear nor substantiated in a scientific manner. In plaintiff's view these requested tests are not intended to supplement the testing report, but seemed designed to annul it. During an oral hearing held on June 08, 2011 organized by the Service Center plaintiff was prevented by the senior expert and the Service Center from interrogating the authors of the testing report. Nevertheless, one of the authors said that their work and conclusions were correct or they would not have signed it.

Currently, plaintiff is trying to convince the court to listen to plaintiff's arguments.

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of

United States Patent and Trademark Office, Department of Commerce

Litigation before the first instance is pending since more than 4 years. During the court proceedings the judge in charge was absent for two and four months to attend IP training in Beijing, during which the proceedings were put on hold.

Conclusion:

1. An expert appointed by the court should be independent. An expert should not be employed or have been employed in the industry covered by the patent in question, since such companies normally are often competitors of the patent owner. Experts in this field only need to be familiar with advanced chemical testing. Appropriately, an appointed expert organization should have test equipment, skilled personnel who operate the equipment and experts under one roof.

2. In a normal procedure, an appraisal document (whether as the final expert report or as an interim testing report) delivered by an appraisal institution to a court represents and reflects the position and opinion of the appraisal institution (including its experts, similarly hereinafter). In other words, the appraisal institution should accept and concur with what is written in the appraisal document, or it would not have delivered the appraisal document to the court and the parties for cross-examination purposes.

An appraisal institution, following receipt of a testing report from the testing institution, should resolve on its own any doubt regarding the report through internal consultations with the testing institution before submitting the report to the court and the parties. Once the appraisal institution formally submits the report to the court and the parties, the report becomes a formal document acknowledged and accepted by the appraisal institution and the appraisal institution should not on its own accord deny and overturn the basic position and conclusion of the test report.

In such normal procedures, once a testing report enters into the cross-examination process, the appraisal institution should stand by the testing results to face the cross-examination of the parties. Any party who intends to overturn any part of the testing report not in its favor should present irrefutable counterevidence based on the principle of "the burden of proof lies on the one making the claim", rather than simply questioning the testing results formally submitted by the appraisal institution.

In this case, however, what the appraisal institution did is contrary to what should happen in a normal procedure. At a time when the appraisal institution has already submitted via the court the test report to the two parties for cross-examination and the parties have also submitted their respective cross-examination opinions to the court, the appraisal institution did not defend the testing results, provide explanations or refute the negative cross-examination opinion of the defendant; instead, it openly questioned and opposed the testing results by first proposing a supplementary test (as indicated in its letter to the court dated 24 August 2010), and then totally denying the original testing results and suggesting a new test using a new method (as indicated in its letter to the court dated 10

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January 2011). The appraisal institution on the one hand submitted the test report to the court and the parties as its official work product, but on the other hand openly rejected and refused to adopt the conclusion of the test report. In other words, in the cross-examination regarding the test report, the appraisal institution, which should have been the party to answer cross-examination questions and stand by the test report, ended up being the party to ask cross-examination questions and to openly oppose and reject the test report.

The basic conclusion of the test report is in favor of the plaintiff, not the defendant, and so once the appraisal institution submitted the report via the court to the parties for cross-examination, a confrontation would certainly arise in which the plaintiff would accept the testing results and the defendant would oppose it, as has been evidenced by the cross-examination opinion of each of the two parties. Under this circumstance, the way in which the appraisal institution handled the test report is contrary to the normal procedure. The resulting paradox and role reversal will undoubtedly impact the fairness and neutrality of any subsequent test and appraisal procedures and thereby prejudice the substantive rights of the plaintiff.

The experts' open denial of the existing testing results has effectively turned them into allies and "spokespersons" for the defendant who has questioned and opposed the testing results. Further, in a normal procedure, the defendant will be required to provide solid counterevidence in order to object existing testing results, and not by simply questioning it. However, this case demonstrates that an expert may, by using his special position and role, refuse to adopt the testing results, merely by expressing doubts about it without no supporting counterevidence. As a result, the defendant, without having to provide any counterevidence on its part, can make use of the expert's opinion to simply overturn the testing report which the Service Center has formally submitted to the court as its work product.

04 November 2011

Hernandez, Jesus

From: George Eakin <george@osborneindustries.com>
Sent: Tuesday, October 18, 2011 6:30 PM
To: IP Policy
Subject: 76 Fed. Reg. 64075

Greetings USPTO:

It is my understanding that the USPO is accepting public comments on protecting and defending Corporate IP in China (76 Fed. Reg. 64075). Osborne Industries is an innovative manufacturer located in Osborne, Kansas. We have two segments to our business which include custom plastic molding and manufacturing of a proprietary line of agricultural equipment primarily for the swine industry. Osborne Industries began exporting our livestock equipment products to China in 2001 via a sales/Marketing company that was located in Shanghi, China. We have recently established (June 2011) a majority ownership in a Chinese company in order to compete directly for the Chinese swine equipment market. Osborne Industries' equipment is used for electronic performance testing of animal genetics and electronic animal feeding and management systems. Therefore, we have much technology invested in our products and their operation.

As many people know, the Chinese government is seeking ways to improve their agricultural efficiencies in an effort to feed their large population. Currently, China ranks the lowest in pig production capabilities and genetics worldwide. The Chinese government has recognized that in order to improve their production capabilities, outside foreign assistance will be needed. In 2001, Osborne Industries sold our Feed Intake Recording Equipment (FIRE) system to a provincial government entity to prove that our equipment was beneficial in assisting China in their efforts to improve swine genetics and animal production. We continued to sell our products to the government in several other installations too. However, the provincial government entity reverse engineered our FIRE system and created a new company Guangdong Agriculture Machinery Research Institute who then patented our product. This was also done with our Electronic Sow Feeding (ESF) system.

In 2008, we were notified that Guangdong Agriculture Machinery Research Institute patented our products and we filed suit in the Chinese legal system. We hired Chinese legal representatives to conduct the office actions needed to revoke the issue of the Chinese patents. We contacted our State and Federal Congressional representatives along with Federal Agencies for assistance, but to no avail. Our legal efforts continued for three years without success owing to the fact that the Chinese Courts needed the original shipping bill of lading for our 2001 shipment to the provincial government entity. We had copies of the documents, however, the original documents were retained by the Chinese Customs department and would not be released to us. We requested the courts to ask for the documents and were denied. This stonewalling and fear of placing one Chinese entity against another forced us to accept the judge's decision of denial to revoke the patent issue. During the court proceedings, the judge indicated that a bribe would be necessary to settle the issue. We did not consider this option owing to its potential outcomes. This shows that the Chinese legal system remains corrupt when dealing with foreign entity IP. Since this time, additional patents have been issued on our products both for items that we have sold into China and items listed on our website and have not been sold into China.

There appears to be an attempt to allow companies to conduct "squatting" on other foreign entity's IP. We experienced this too during the legal process when Guangdong Machinery Research Institute offered us the opportunity to buy our IP from them to enable us to sell our equipment into China. The Chinese patent system does not accept existing worldwide applications of technology and therefore allows Chinese companies to patent items that have been known in the rest of the world for years. It is evident that the Chinese government is trying to reign in these rouge justices and under the table dealings, but it will take time. However, in the meantime, US companies like Osborne Industries will continue to sell our products in China knowing that it may become necessary for us to acquire much more assistance

from the USPTO and our Government Trade Department to overcome the barriers that may block us from selling our products against our own products.

If you have any further questions or need additional information, please do not hesitate contacting me. Thank you for taking time to listen to our China IP story.

Best Regards,
Osborne Industries, Inc. - *A 100% Employee Owned Company*

George R. Eakin
President, COO



2010 Kansas Exporter of the Year

120 North Industrial Ave., Osborne, KS 67473, USA

Voice: 785-346-2192 **Fax:** 785-346-2194

E-mail: george@osborneindustries.com

Website: www.osborneindustries.com

The Osborne Quality System is Certified to ISO 9001

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1150 18th Street, NW
Suite 700
Washington, DC 20036

p. 202/872.5500
f. 202/872.5501

November 4, 2011

Elizabeth Shaw
Supervisory Intellectual Property Research Specialist
Office of the Administrator for Policy and External Affairs, USPTO
US Department of Commerce
600 Dulany Street, 10th Floor West
Alexandria, VA 22313-1450

VIA EMAIL: IP.Policy@uspto.gov

Re: Request for Comments on Intellectual Property Enforcement in
China

Dear Ms. Shaw:

The Business Software Alliance ("BSA") appreciates the opportunity to make this submission in response to the United States Patent and Trademark Office's Request for Comments on Intellectual Property Enforcement in China. BSA represents more than 25 software and computer companies¹ that collectively hold hundreds of thousands of patents around the world. Our members invest billions of dollars in research and development every year, and they regularly rely on patents to protect their innovations against misappropriation. As part of their global presence, BSA members have a strong interest in obtaining and, if necessary, enforcing their patent rights in China.

Every one of BSA's member companies relies on intellectual property protection for the viability of its business. Patents, copyrights, and trademarks are indispensable both to provide incentives to innovate and

¹ *The Business Software Alliance (www.bsa.org) is the leading global advocate for the software industry. It is an association of nearly 100 world-class companies that invest billions of dollars annually to create software solutions that spark the economy and improve modern life. Through international government relations, intellectual property enforcement and educational activities, BSA expands the horizons of the digital world and builds trust and confidence in the new technologies driving it forward. BSA's members include: Adobe, Apple, Autodesk, AVEVA, AVG, Bentley Systems, CA Technologies, CNC/Mastercam, Cadence, Compuware, Corel, Dell, Intel, Intuit, Kaspersky, McAfee, Microsoft, Minitab, Progress Software, PTC, Quark, Quest Software, Rosetta Stone, Siemens PLM, Dassault Systemes SolidWorks, Sybase, Symantec, and The MathWorks.*

to protect assets against misappropriation and infringement. In recent years, patents have become a more important form of protection for software developers. As a result, all BSA members have been very active in filing and obtaining patents in the United States as well as all major international markets, including China.

An effective patent system that promotes innovation in computers and software has certain essential elements. Patents must be available without limitations on classes of invention or preconditions, including where the invention occurred, the nationality of the applicant, and how the invention is to be commercialized. In addition, the application and examination process has to be predictable, transparent, and rigorous to ensure patents are granted for only meritorious inventions. BSA submitted comments to the Chinese government on each of these issues in 2007 when China was promulgating rules on the operation of its patent system. Finally, the ability to enforce a patent against infringers is critically important to preserving the integrity and efficacy of the system.

With these considerations in mind, it is our understanding that in recent years all BSA members have been actively applying for patent protection in China. None of our member companies report significant problems in obtaining patents in China. Because many of our members have only recently been developing their patent portfolios in China, they have not had extensive experience in enforcing their patent rights within China.

While BSA members have limited experience enforcing patents in China, they do have a great deal of experience enforcing copyrights within the country. BSA members have worked diligently with the Chinese government to strengthen China's copyright laws and litigation procedures.

Transparency, due process, and the ability to enforce judgment awards are a few of the issues that BSA members have encountered in the copyright area. BSA members are therefore concerned that as they increase their patent enforcement efforts in China, they will confront similar issues.

The comments set forth below draw from BSA members' collective experiences and understandings of the Chinese legal system when enforcing intellectual property rights.

As an initial step, it is imperative that the Chinese system for enforcing patents be transparent, including:

- a clearly articulated standard for determining whether a court will accept or reject a case;
- a system that allows for the appeal of decisions to reject a case;
- a clear case schedule identifying when the party bearing the burden of proof must present its evidence;
- a process that requires that written decisions to reject a case be provided to the plaintiff and that judicial decisions be published; and
- a regime that includes stronger and more transparent rules concerning evidence collection and preservation.

Such measures are important to ensure that China's patent litigation process is both objective and fair. Under current practice in China, courts first decide whether to "accept" or "reject" a case based on the initial complaint, but Chinese courts have not articulated a clear standard for determining the types of allegations and evidence that are required for a case to be accepted. This inhibits enforcement efforts. Inventors need predictable criteria when deciding whether to initiate a case. BSA members believe China should articulate a clear standard for determining whether a court will accept or reject a case.

The decision by the court to reject a case is not appealable. This leaves parties without any recourse if a court makes a mistake that causes it to reject a case. Accordingly, parties should have an opportunity to appeal a decision to reject a case based on the initial complaint. Not only are decisions to reject not appealable, courts oftentimes fail to provide written notice that a case has been rejected. Thus, the fact that a decision to reject a case is not appealable and that a plaintiff may not even receive a written notification of the rejection makes it very difficult for an inventor to invest the resources required to initiate a case. China should ensure that decisions to reject a case are appealable and that written decisions to reject a case are provided to the plaintiff.

Once a court decides to accept a case, the court should provide a clear case schedule identifying when the parties bearing the burden of proof must present their evidence to the opposing side. Such a schedule would allow litigants to properly plan and allocate their resources at the appropriate time. A complete schedule will also prevent parties from

being caught by surprise, which often happens when deadlines are not clearly identified.

BSA members believe that judicial decisions should be published. By publishing decisions, future litigants will have the ability to craft effective arguments building on arguments that were successful in the past. Moreover, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states that “decisions on the merits of a case shall preferably be in writing and reasoned.”

Stronger and more transparent rules concerning foreign translations of documents, evidence collection, and preservation are also important. In patent cases, foreign language technical documents can be very important to a party’s case. Chinese courts, however, frequently make it very difficult for parties to submit into evidence foreign translations of these documents. China should promulgate clear and uncomplicated rules for submitting translations.

Litigants oftentimes require access to their opposing party’s files to properly enforce and defend patent cases. It is very difficult for inventors to develop the evidence they need to prove their case because China does not have a robust discovery system. China should establish rules for exchanging relevant information between parties.

Our experience in enforcing copyrights highlights the need for clearer and more comprehensive evidentiary rules. It is very hard for a copyright owner to obtain an order for preservation of evidence. Under current Chinese practice, courts require a copyright plaintiff to submit substantial evidence before the court will order preservation of additional evidence. This “high-showing” requirement, given that gathering such evidence with a court order is very difficult, imposes a substantial hurdle to enforcement actions.

China has no mechanism for ensuring that confidential information exchanged between parties during litigation is protected from public disclosure. Oftentimes, patent cases involve highly valuable confidential and trade secret information. The threat that information a plaintiff provides to a court or the defendant may become public poses a serious impediment to enforcing patent rights. China should establish a system that ensures confidential information is protected.

In order to have a robust and effective patent system, there must be adequate remedies for bringing a case against an infringer. Strong remedies provide motivation for inventors to innovate, patent their inventions, and prosecute others that use their technology without permission. Strong remedies also act as a deterrent against would-be infringers. The remedies of the Chinese system should include:

- Damages awards that motivate inventors to enforce their patents and that also deter potential infringers;
- Clear criteria for obtaining injunctions against infringers; and
- Simple mechanisms for enforcing damages awards and injunctions against companies that attempt to avoid the judgment.

BSA members believe that damages awards must be sufficient to compensate the patentee for the injury caused by the infringer and that the damages award must also act as a deterrent against potential infringers.

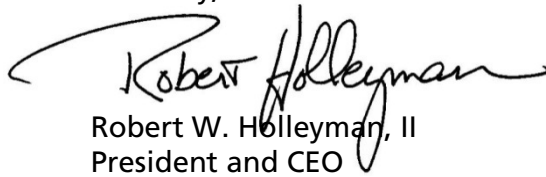
The threat of an injunction, in appropriate circumstances, can be a very effective deterrent. Under current Chinese procedures, it is not clear when injunctions will issue and the kinds of evidence required for the court to make its decision on whether to grant an injunction. China should clearly identify the criteria an inventor must meet to obtain an injunction.

Based on our experience in copyright enforcement in China, there is no specific deadline for the court to conclude an infringement suit when a foreign party is involved. In many instances, cases drag on for a very long time. This unreasonably delays the resolution of the case and increases the costs of enforcement on holders of intellectual property rights.

Finally, it is currently very difficult for successful plaintiffs to enforce damages awards and court orders against companies that move to a different province or reincorporate under a different name to avoid enforcement. China should ensure that successful plaintiffs are easily able to enforce their injunctions and damages awards regardless of where the defendant is located or whether the defendant has changed names.

BSA appreciates the opportunity to comment on this issue. Any questions or further communications should be directed to Tim Molino, Director, Government Relations, BSA (timothym@bsa.org).

Sincerely,



Robert W. Holleyman, II
President and CEO



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.

Pharmaceutical Research and Manufacturers of America

950 F Street, NW, Washington, DC 20004 • Tel: 202-835-3400

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-designated 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 (i.e., 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 attorney 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 alternative 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

BY E-MAIL ONLY (IP.Policy@uspto.gov)

Mail Stop OPEA
ATTN: Elizabeth Shaw
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Ms. Shaw:

In response to the USPTO's Request for Comments on Intellectual Property Enforcement in China, we provide the following anonymous remarks on behalf of a medium-sized biotechnology company. We welcome the opportunity provided by the USPTO to offer recommendations for improving the patent enforcement landscape in China.

Our experience has identified a variety of challenges that innovators face with China's patent enforcement systems.

1. Inconsistency of the State Intellectual Property Office of the P.R.C. ("SIPO") and courts in the interpretation of a "functional definition."

During the prosecution stage before SIPO, a "functional definition" is interpreted by SIPO as including all of the embodiments encompassed by the functional definition; but at the enforcement stage, a "functional definition" is interpreted by the court as being limited to those embodiments for which data is provided in the Examples set forth in the patent specification.

2. Narrow scope of granted claims.

The current practice before SIPO is to grant claims limited to exemplified embodiments. In the biotechnology arts, it was in the past routine to obtain claims before SIPO reciting "percent identity" or "percent homology" to a particular protein or DNA sequence. More recently, however, the expression of identity and/or homology (no matter how limiting the required percent identity or homology) has not been permitted.

3. Limitation on amendments.

During a patent invalidation trial, a patentee seeking to enforce a patent has only one opportunity to amend the claims before SIPO. However, any amendment must be limited to the specific elements recited in the claim set as originally granted, i.e. by deletion of claims, deletion of technical solutions or combination of technical solutions, regardless of the full scope of the patentee's disclosure.

4. Availability of doctrine of equivalents.

The availability and application of the doctrine of equivalents to claims in enforcement actions in China is at present unclear. This approach by the courts increases the risk to the innovator that a challenger might unfairly design around the claims and avoid liability for appropriating the innovator's invention.

5. Limitations on divisional filings.

Divisional applications before SIPO may only be filed during the pendency of the original national patent application, and therefore a patentee has little ability to adapt the scope of the claims to accommodate subsequent changes in patent practice or case law or unanticipated activity by infringers.



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,

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

Champion, China Issues Project, Interpat