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COUNTERFEIT PHARMACEUTICALS IN CHINA: COULD CHANGES BRING STRONGER PROTECTION FOR INTELLECTUAL PROPERTY RIGHTS AND HUMAN HEALTH?

Dina M. Bronshtein[†]

Abstract: Although China seeks to improve its image as a legitimate participant in the global intellectual property (“IP”) market, Chinese companies continue to produce more than thirty percent of the counterfeit drugs circulating in the world today. The counterfeit pharmaceutical industry profits from efficient and cost-effective production systems by producing counterfeits at an exceedingly low cost. This poses a serious problem because the production and sale of counterfeit drugs leads to negative economic and social health-related effects. China’s existing penalties for counterfeit pharmaceutical production are considered a mere cost of doing business in China, rather than a deterrent from engaging in counterfeiting. China’s national government has taken several steps to fight against IP infringement, but despite this effort, the growing power and autonomy of local governments has complicated and exacerbated the problem.

In order to become a legitimate and reputable force in the international economy, China must take greater steps to limit the production and sale of counterfeit pharmaceuticals. First, China must amend its laws to include penalties that will effectively deter actors from entering the counterfeit market. Second, China must allocate a significant amount of resources to the judicial system to ensure that adjudication is effective and efficient. Third, China must fight localized corruption at its source to increase enforcement of IP rights. Specifically, an agency should be created to target local corruption and to disestablish the counterfeit pharmaceutical market. This agency should have investigative and auditing power and should work to educate both the public and the business community on the problems posed by counterfeit pharmaceuticals and the means used to counter them.

I. INTRODUCTION

The World Health Organization (“WHO”) defines a counterfeit drug as “a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source.”¹ China is one of the world’s top producers of both legitimate and counterfeit pharmaceuticals.² In 1980, China took initial significant steps to improve its IP climate when it joined

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¹ INT’L FED’N OF PHARM. MFRS. & ASSOC., COUNTERFEIT MEDICINES: AN UPDATE ON ESTIMATES 1 (2006), http://www.ifpma.org/Issues/fileadmin/templates/ifpmaissues/pdfs/IMPACT_counterfeit_estimate_15Nov06.pdf.

² See Maria Nelson et al., *Counterfeit Pharmaceuticals: A Worldwide Problem*, 96 TRADEMARK REP. 1068, 1089 (2006).

the World Intellectual Property Organization (“WIPO”).³ Since this important development, China has adopted and amended its IP law, signed several treaties, and joined international organizations to work towards establishing a “made by China” label, rather than remaining with the “made in China” label.⁴ These changes have led to fast-paced growth of intellectual property activity.⁵ In fact, according to a WIPO report, China has become the third largest recipient of patent filings with a filing increase of almost thirty-three percent in 2004 alone.⁶ Although these numbers seem promising, China’s prominent role in the counterfeit drug market reveals its ongoing inability to enforce IP rights or to prosecute infringement through administrative, civil, or criminal mechanisms.⁷

Worldwide, the counterfeit drug market accounts for approximately forty billion dollars in annual sales.⁸ China is a lead actor in this market, and its role will arguably only increase in the future.⁹ Although there are significant profits that can be earned from participation in the counterfeit drug market, counterfeiting also results in physical harm or death to thousands of people globally,¹⁰ as well as decreased confidence in the Chinese economy and stifled innovation.¹¹ The Chinese government could arguably approach this problem head-on by amending legislation and increasing enforcement efforts. Additionally, it could work to eliminate the local government corruption that undermines existing counterfeit drug regulations.¹²

This comment discusses the issues revolving around China’s counterfeit drug industry and provides suggestions as to how the Chinese

³ Permanent Mission of P.R.C. to the U.N. Office at Geneva and Other Int’l Orgs. in Switz., *The Cooperation Between China and the World Intellectual Property Organization* (Apr. 19, 2004), <http://www.china-un.ch/eng/zmjg/jgjbic/t85562.htm>.

⁴ See Jayanthi Iyengar, *Intellectual Property Piracy Rocks China Boat*, ASIA TIMES, Sept. 16, 2004, available at <http://www.atimes.com/atimes/China/FI16Ad07.html>; see also Nelson et al., *supra* note 2, at 1089.

⁵ See generally HUAIWEN HE & PING ZHANG, *IMPACT OF THE INTELLECTUAL PROPERTY SYSTEM ON ECONOMIC GROWTH, COUNTRY REPORT-CHINA*, http://www.wipo.int/about-ip/en/studies/pdf/wipo_unu_07_china.pdf (last visited Feb. 8, 2008) (discussing development of Chinese IP System).

⁶ World Intellectual Property Organization [hereinafter WIPO], *WIPO Patent Report: Statistics on Worldwide Patent Activities*, at 10 (2007), available at http://www.wipo.int/export/sites/www/freepublications/en/patents/931/wipo_pub_931.pdf.

⁷ U.S. Dep’t. of Comm. Int. Trade Admin., *IPR Toolkit: Protecting Your Intellectual Property Rights (IPR) in China* (Dec. 2005), http://beijing.usembassy-china.org.cn/protecting_ipr.html.

⁸ Ying Huang, *AstraZeneca Adopts Digital Security to Deter Chinese Counterfeiting*, PHARMAASIA NEWS, Sept. 5, 2007, <http://fdcalerts.typepad.com/asia/2007/09/astrazeneca-ado.html>.

⁹ See Peggy B. Hu & Berta Gomez, *Public Safety Jeopardized by Chinese Counterfeiters*, *Experts Say* (May 20, 2005), <http://usinfo.state.gov/eap/Archive/2005/May/20-45620.html>.

¹⁰ *Id.*

¹¹ See Iyengar, *supra* note 4.

¹² See Nelson et al., *supra* note 2, at 1089.

government can better address this problem. Part II discusses the serious health threats posed by counterfeit drugs, introduces a prominent example of drug counterfeiting, and presents the steps China has already taken to fight against IP infringement. Part III describes the body of Chinese law created to confront IP infringement and fight against counterfeiting. Part IV addresses the legal mechanisms used to enforce these IP laws and discusses specific issues that hinder deterrence of pharmaceutical counterfeiting. Finally, Part V suggests possible means by which the Chinese government could improve enforcement of IP laws in order to reduce China's production and sale of counterfeit drugs.

II. BACKGROUND ON PHARMACEUTICAL COUNTERFEITING

Countries around the world have communicated their strong opposition to drug counterfeiting, despite the fact that counterfeiting has the ability to yield high economic gains for those who do business in the industry.¹³ The rise of counterfeit drugs has caused a decrease in innovation and investment in legitimate pharmaceutical companies. It has also caused a wide array of social and economic problems for China.¹⁴

A. *Pharmaceutical Counterfeiting Causes Serious Physical and Economic Harm*

According to WHO, counterfeit drugs account for ten percent of the world's pharmaceuticals, though this number may be as high as sixty percent in some developing countries.¹⁵ Counterfeit drugs will be worth approximately seventy-five billion dollars globally by 2010.¹⁶ Due to China's significant contribution to this mass production, the United States has placed China on its "priority watch list"¹⁷ of countries failing to protect IP rights adequately and reduce infringement levels significantly.¹⁸

¹³ See Jim Hilboldt, *Counterfeit Medicines Outside the United States: Challenges and Responses*, in PHARMACEUTICAL LAW 2006: ACROSS THE PRODUCTION LIFE CYCLE 869, 874 (PLI Patents, Copyrights, Trademarks, & Literary Property, Course Handbook Series, 2006).

¹⁴ See Nelson et al., *supra* note 2, at 1072.

¹⁵ See U.S. Chamber of Commerce View on China's Enforcement of Intellectual Property Rights and The Dangers of the Movement of Counterfeited and Pirated Goods into the U.N., Testimony Before the U.S.-China Economic and Security Review Commission (June 7, 2006) [hereinafter U.S. Chamber of Commerce] (statement of Myron Brilliant, Vice-President, East Asia U.S. Chamber of Commerce.), available at http://www.uscc.gov/hearings/2006hearings/written_testimonies/06_06_07wrts/06_06_7_8_brilliant_myron.php.

¹⁶ WHO, Counterfeit Medicines (Nov. 14, 2006), <http://www.who.int/mediacentre/factsheets/fs275/en/>.

¹⁷ The United States places countries that have failed to meet its IP protection standards on a "priority watch list." See OFFICE OF THE U.S. TRADE REPRESENTATIVE, SPECIAL 301 REPORT: EXECUTIVE

The counterfeit pharmaceuticals market presents a serious health risk to both Chinese citizens and to the international community. This growing problem is due to the fact that approximately fifty percent of China's drug supply is counterfeit.¹⁹ According to Shenzhen Evening News, a Chinese government-run news station, approximately 192,000 people died in China in 2001 due to consumption of counterfeit drugs.²⁰ In considering this figure, it is important to remember that although this may not seem significant in comparison to China's population of over one billion, the actual death toll is likely to be much higher than the reported number.²¹

Counterfeit drugs cause fatalities through both immediate and latent effects.²² For example, some counterfeits can accelerate the growth of drug-resistant virus strains.²³ This occurs when the counterfeit contains too little of the necessary active ingredients making up the legitimate drug and, therefore, does not kill all the disease agents, causing the strains to spread.²⁴ This problem is especially evident in developing countries that lack the resources and political will to fight against counterfeiting; residents of such countries are often those that need the most legitimate medical attention.²⁵

The detrimental economic effects of pharmaceutical counterfeiting reach beyond the borders of the source country.²⁶ Producers of counterfeit

SUMMARY 18-19 (2007), http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file473_9336.pdf [hereinafter SPECIAL 301 REPORT]. The Special 301 Report is released annually by the Office of the U.S. Trade Representative. It reports on the adequacy and effectiveness of intellectual property ("IP") rights protection of U.S. trading partners. See BeSpacific, USTR's 2007 Special 301 Report (Apr. 30, 2007), <http://www.bespacific.com/mt/archives/014712.html>.

¹⁸ See U.S. Dept. of State, China Has High Rate of Intellectual Property Infringement (Apr. 29, 2005), <http://usinfo.state.gov/usinfo/Archive/2005/Apr/29-580129.html>.

¹⁹ Amy Reeves, *Clamping Down on Counterfeit Drugs; Billions Are at Stake: FDA, Drug Makers Move to Reduce the Number of Fakes That Hit the Market*, INVESTOR'S BUS. DAILY, Oct. 20, 2003, at A9.

²⁰ Todd Datz, *Faked in China*, CSOONLINE.COM, Jan. 1, 2006, http://www.csoonline.com/read/010106/faked_china.html. See also GRAHAM SATCHWELL, A SICK BUSINESS: COUNTERFEIT MEDICINES AND ORGANISED CRIME 44 (2004), available at <http://www.stockholm-network.org/downloads/publications/2b74e489-Sick%20Business.pdf>. In fact, it has been estimated that there is on average between 200,000 and 300,000 reported deaths in China each year due to counterfeit or substandard medicine. See Peter Pitts, President, Ctr. for Med. in the Pub. Interest, Testimony: Counterfeit Drugs and China (May 31, 2006), <http://www.cmpi.org/TestimonialsDetail.asp?contentdetailid=99&contenttypeid=8&page=1>.

²¹ See Pitts, *supra* note 20.

²² See Lisa Lerer, *Bitter Pills: Counterfeit Drugs Manufactured in China Are Landing in Some of the Poorest Areas in the World, Killing Those Most Desperate for Medical Attention*, IP LAW & BUS., Dec. 1, 2006, at 32.

²³ *Id.*

²⁴ *Id.* For example, WHO and the U.S. Centers for Disease Control believe that substandard or ineffective medicines have contributed to the emergence of drug-resistant strains of cholera, salmonella, tuberculosis and other diseases. See Hu & Gomez, *supra* note 9.

²⁵ See Hu & Gomez, *supra* note 9, at 1-2.

²⁶ See Nelson et al., *supra* note 2, at 1072.

drugs do not comply with safety regulations and do not pay taxes on their goods.²⁷ This reduces government revenue because legitimate drug producers are less likely to enter the market and thus pay taxes if that market is highly saturated with counterfeits.²⁸ Additionally, the counterfeit drug market stifles investment and innovation.²⁹ The cost of investigating and prosecuting infringers is expensive for both companies and the government.³⁰ In countries where counterfeiting is widespread, it can cost millions of dollars annually to track down infringers and pay the litigation costs associated with prosecuting them.³¹ Often, even if a company prevails in litigation, the financial results are far from cost-effective.³² These expenses will likely deter new companies from entering the pharmaceutical market and existing companies from investing in innovative efforts that could lead to life-saving discoveries. This results in stifled pharmaceutical innovation, which harms both economies and public welfare globally.

China's efforts to avoid such harm and legitimize its IP market are evident in the struggles faced by Pfizer Pharmaceuticals ("Pfizer") in China. Moreover, Pfizer's effort to protect its IP rights ("IPR") illustrates the difficulty of obtaining IP protection in China and China's efforts made to become a respected member of the international IP community.

B. The Pfizer Pharmaceuticals Case Reveals the Magnitude of the Counterfeiting Problem and China's Effort to Develop IP Enforcement

In recent years, several cases have demonstrated overall improvement in China's IPR enforcement regime. The Pfizer case, which involved several Chinese companies' attempts to enforce what they claimed to be their IPR against Pfizer, illustrates such improvement and the resulting increased confidence in Chinese enforcement of IPR within the international community.

The Chinese State Drug Administration approved the use of Pfizer's drug Viagra in China on July 2, 2000.³³ At the time, however, China's State Intellectual Property Office ("SIPO") had not yet granted Pfizer a patent for

²⁷ *Id.*

²⁸ Jamie Miyazaki, *Faking It Gucci Style*, ASIA TIMES, Feb. 6 2004, available at http://www.atimes.com/atimes/Global_Economy/FB06Dj01.html.

²⁹ See Nelson et al., *supra* note 2, at 1072.

³⁰ See U.S. Chamber of Commerce, *supra* note 15, at 3.

³¹ *Id.*

³² *Id.*

³³ See Jeffrey A. Andrews, *Pfizer's Viagra Patent and the Promise of Patent Protection in China*, 28 LOY. L.A. INT'L & COMP. L. REV. 1, 10 (2006).

sildenafil citrate, the active ingredient in Viagra.³⁴ In China, access to Viagra was available by prescription from senior physicians only, and distribution was confined to hospital pharmacies.³⁵

In May 2000, the promise for potential growth of China's Viagra market immediately attracted the interest of counterfeit producers. At this time a Chinese pharmaceutical company began illegally manufacturing sildenafil citrate.³⁶ This company relied upon Pfizer's SIPO disclosures to obtain information about Viagra's active ingredient and to seek to obtain a patent for this ingredient itself.³⁷ This led to a vast increase in the sale of Viagra in sex shops, airports, and pharmacies all over China.³⁸ In fact, just six months after Pfizer introduced Viagra to the Chinese market, an estimated ninety percent of Viagra pills sold in Shanghai were counterfeit.³⁹ Such counterfeit distribution caused Pfizer to experience significant market pressure.⁴⁰ Pfizer subsequently took steps to combat these counterfeit sales. However, it was not until September 19, 2001, when SIPO issued Pfizer a patent for the active ingredient in Viagra,⁴¹ that legal action commenced against the widespread counterfeiting. At that time, a group of twelve Chinese drug companies petitioned the Patent Reexamination Board to invalidate Pfizer's patent, leading to a series of IP infringement trials.⁴²

Such actions signaled an important change in Chinese IP enforcement. Until this time, the Chinese producers and sellers of pharmaceuticals dealt with similar situations by engaging in counterfeit activities instead of turning to legal proceedings.⁴³ Specifically, if there was a conflict regarding IPR, instead of trying to enforce what they believed to be their patent or trademark, such parties often allowed the opposing party to obtain all legal rights and then engaged in infringement by producing and selling the given drug as a counterfeit. Petitioning to the Patent Reexamination Board was a new approach to competing with foreign products.⁴⁴ This change was

³⁴ *Id.*

³⁵ See Shi Pengyun, *Viagra No Longer Hard to Get*, CHINA DAILY, Feb. 7, 2002, available at http://www.chinadaily.com.cn/en/doc/2002-02/07/content_105885.htm.

³⁶ See Andrews, *supra* note 33, at 10.

³⁷ *Id.* at 10-11.

³⁸ *Id.* at 11.

³⁹ Elaine Kurtenbach, *China Court Upholds Pfizer's Viagra Patent*, CBSNEWS.COM, June 5, 2006, <http://www.cbsnews.com/stories/2006/06/05/ap/business/mainD811U0U00.shtml>.

⁴⁰ See Andrews, *supra* note 33, at 11.

⁴¹ *Id.*

⁴² *Id.*

⁴³ See *id.* at 12.

⁴⁴ See *id.*

further demonstrated by the decision of the Chinese patent review board,⁴⁵ which decided to uphold Pfizer's patent rights for Viagra.⁴⁶

Similarly, in 2005, Pfizer also successfully fought to protect another drug, Lipitor, from Chinese counterfeiters.⁴⁷ Three Chinese businesses and eleven Chinese individuals were indicted for their involvement in a forty-two million dollar conspiracy to sell counterfeit Lipitor.⁴⁸ As part of this effort, the Food and Drug Administration in the United States recalled over eighteen million Lipitor tablets.⁴⁹ This enormous recall was due to the significant problem associated with deciphering counterfeit drugs from legitimate ones once they were released into the public market.⁵⁰

In response to these reoccurring cases, Pfizer, with the help of the Chinese government, made several efforts to address the counterfeiting problem in China. For example, Pfizer opened a testing facility in Dalian, China⁵¹ and formed an alliance with the Shanghai Municipal Food and Drug Administration to detect and stop counterfeiting.⁵² Pfizer also signed two agreements with the Chinese state government. These agreements laid out the parties' joint efforts to fight against the production of counterfeit drugs through the use of investigation and drug testing.⁵³ Through this initiative, Chinese officials recovered 600,000 counterfeit Viagra labels and packaging, 440,000 counterfeit Viagra tablets, and 260 kilograms of raw materials used to manufacture counterfeit drugs.⁵⁴ Also, in 2001, the Chinese government closed down 1300 companies for counterfeiting, while investigating 480,000 cases of counterfeit drugs worth a combined total of fifty-seven million dollars.⁵⁵ Furthermore, the Chinese State Food and Drug Administration announced that it had banned 114,000 unlicensed drug manufacturers and

⁴⁵ In 2004, the Reexamination Board held that the technical openness of the patent specification was incompatible with Pfizer's claim to rights and Pfizer lost at the administrative level; however this decision was overturned. *Id.*

⁴⁶ See Nelson et al., *supra* note 2, at 1093.

⁴⁷ *Problem of Counterfeit Drugs: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Resources of H. Comm. on Gov't Reform*, 109th Cong. (2005) (statement of Randall W. Lutter, Acting Assoc. Comm'r for Policy and Planning, Food and Drug Administration).

⁴⁸ *Id.*

⁴⁹ See Hilboldt, *supra* note 13, at 888.

⁵⁰ See Nelson et al., *supra* note 2, at 1070.

⁵¹ See Omario Kanji, Note, *Paper Dragon: Inadequate Protection of Intellectual Property Rights in China*, 27 MICH. J. INT'L L. 1261, 1268 (2006).

⁵² Medical News Today, *Pfizer Signs Agreement with Shanghai Government to Enhance Protection of Patients*, May 19, 2004, <http://www.medicalnewstoday.com/articles/8476.php>.

⁵³ See Hu & Gomez, *supra* note 9.

⁵⁴ See Lutter, *supra* note 47.

⁵⁵ See Pitts, *supra* note 20.

shut down 461 Chinese pharmaceutical factories between January and November of 2005 alone.⁵⁶

The Chinese state government's efforts to more closely regulate IPR through increased investigation and litigation demonstrates its willingness to improve its national IP climate.⁵⁷ To further effectuate this goal, as detailed below, China has joined several international IP organizations and signed various international treaties.

C. *China Complies with the Express Requirements of Various International IP Agreements*

In recent years, the Chinese national government has communicated a strong desire to encourage innovation through increased enforcement of IPR.⁵⁸ During this time, China has joined international organizations and signed several treaties in order to solidify its position in the global IP market.⁵⁹ However, China has continuously struggled to meet the requirements of these international instruments.⁶⁰

After joining WIPO in 1980,⁶¹ China continued its efforts towards becoming a participant in the international IP market by joining the Paris Convention on Industrial Property in March of 1985 and signing the Patent Cooperation Treaty in 1994.⁶² Additionally, in 1990, China agreed to register all trademarks with the International Bureau of WIPO through its accession to the Madrid Trademark Agreement.⁶³ Finally, on December 1, 2001, China officially became a member of the World Trade Organization ("WTO")⁶⁴ and, at this time, became subject to requirements laid out in the

⁵⁶ *Id.*

⁵⁷ See Kristy Barnes, *China Drug Safety Crackdown Continues*, PACKWIRE, Nov. 6, 2007, <http://www.packwire.com/news/ng.asp?n=77257-china-drug-safety-regulation>.

⁵⁸ See Jiang Zhipei, *Recent Developments in China's Judicial Protection of Intellectual Property Rights*, Address at Temple University Law School (Aug. 18, 2008), available at <http://www.chinaiprlaw.com/english/forum/forum43.htm>. See also U.S. Chamber of Commerce, *supra* note 15, at 7.

⁵⁹ See Andrew Evans, Note, *Taming the Counterfeit Dragon: The WTO, TRIPS and Chinese Amendments to Intellectual Property Laws*, 31 GA. J. INT'L & COMP. L. 587, 587-88 (2003).

⁶⁰ See Iyengar, *supra* note 4.

⁶¹ See Jessica Wong, *The Challenges Multinational Corporations Face in Protecting Their Well-Known Trademarks*, 31 BROOK. J. INT'L L. 937, 943 (2006). WIPO is a specialized agency of the United Nations, dedicated to the development of an accessible and balanced international IP system. See WIPO, *What is WIPO?*, http://www.wipo.int/about-wipo/en/what_is_wipo.html (last visited Oct. 9, 2007).

⁶² See Wong, *supra* note 61, at 943.

⁶³ *Id.*

⁶⁴ See generally World Trade Organization [WTO], *Protocol on Accession of the People's Republic of China*, WT/L/432 (Nov. 23, 2001).

Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”).⁶⁵

China has amended its IP laws and regulations several times in order to comply with requirements of these international agreements; however, it continues to struggle to make the requisite changes to its administrative and judicial bodies. Specifically, as discussed in further detail below, although the applicable laws have been altered to meet international requirements, China continues to lack full implementation of such laws.⁶⁶ TRIPS requires WTO members to protect IPR by promulgating laws that are stringent enough to deter people from engaging in infringement.⁶⁷ However, it is debatable whether China has promulgated appropriate law and policy to effectuate this required deterrent effect.⁶⁸ In order to assess this issue, it is first helpful to consider the actual requirements laid out in the TRIPS agreement.

Article 41(1) of TRIPS mandates that the legal consequences of IP infringement “constitute a deterrent to further infringements.”⁶⁹ This is an important specification of the agreement because it places a significant burden on WTO members to take adequate legal action against IP infringement within its borders. This article does not lay out specific penalties that would “constitute a deterrent,” and, therefore, it is not necessarily clear whether a specific country has met the standards required under TRIPS.

Article 45 of TRIPS mandates that damages in cases of infringement sufficiently remedy the right holder’s injury and should be calculated based on the expense incurred by the patent holder and subsequent profits lost due to lacking sales of the genuine product.⁷⁰ Additionally, Article 61 of TRIPS requires that members provide for criminal procedures and penalties to be applied “at least in cases of willful trademark counterfeiting . . . on a commercial scale.”⁷¹ Because WTO does not define “on a commercial

⁶⁵ See Veronica Weinstein & Dennis Fernandez, *WTO Pushes China Toward Greater IP Protection*, LARTA INST. VOX, July 12, 2004, http://www.larta.org/lavox/articlelinks/2004/040712_wto.asp.

⁶⁶ *Trade with China: Hearing on U.S. Trade with China Before the Subcomm. on Trade of the H. Comm. on Ways and Means*, 110th Cong. (2007) (statement of GERALYN RITTER, Vice President, International Affairs Pharmaceutical Research and Manufacturers Association), available at <http://waysandmeans.house.gov/hearings.asp?formmode=view&id=5458>.

⁶⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 61, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS] (setting forth general provisions, enforcement of and standards concerning IP rights).

⁶⁸ SPECIAL 301 REPORT, *supra* note 17, at 19.

⁶⁹ TRIPS, *supra* note 67, art. 41.

⁷⁰ See *id.* art. 45.

⁷¹ *Id.* art. 61.

scale,” this language gives member states discretion in determining what amount meets this requirement.

Despite possible ambiguities in these articles, TRIPS has played an important role in shaping Chinese IP law. Currently, most observers consider Chinese standards to comply with TRIPS.⁷² However, despite such compliance, the production and sale of counterfeit drugs has not diminished in China due to weak enforcement and deterrence mechanisms in domestic law.⁷³ An assessment of the Chinese IP laws used to protect rights holders from counterfeiting sheds light on this problem.

III. COUNTERFEIT PHARMACEUTICAL PRODUCTION AND SALE VIOLATES CHINESE PATENT AND TRADEMARK LAWS

Individuals or corporations engaged in the production or sale of counterfeit pharmaceuticals in China may be charged with the violation of multiple laws, including those related to IP infringement, pharmaceutical regulations, laws against unfair competition, and custom protections.⁷⁴ Parties harmed by the production or sale of counterfeit pharmaceuticals can also bring an infringement claim under trademark or patent law.⁷⁵ If a person wishes to bring an action against a counterfeiter, these IP laws provide an avenue through which administrative, civil, or criminal action can be taken.⁷⁶

A. *Businesses That Deal in Counterfeit Pharmaceuticals Are Infringing Chinese Patent Law*

If an individual or corporation produces a counterfeit pharmaceutical—one containing active ingredients or substances that are patented under Chinese law—the patent holder can bring a legal action against the manufacturer, seller, or importer of that counterfeit drug.⁷⁷ Such action can be brought through an administrative authority or by an action in

⁷² See *Counterfeiting in China: Roundtable on Intellectual Property Protection as Economic Policy: Will China Ever Enforce Its IP Laws? Before the Cong.-Exec. Comm. on China* (May 16, 2005) (statement of Daniel Chow, Professor, Ohio State University Michael E. Moritz College of Law), available at <http://www.cecc.gov/pages/roundtables/051605/index.php>.

⁷³ *Id.*

⁷⁴ See Hilboldt, *supra* note 13, at 872.

⁷⁵ *Id.*

⁷⁶ See generally *id.* (describing different types of laws violated when counterfeiting takes place); U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

⁷⁷ See Hilboldt, *supra* note 13, at 873.

the people's court.⁷⁸ Patent infringement actions in China are brought to the intermediate people's court and can be appealed to the Supreme People's Court,⁷⁹ whose decision is final.⁸⁰ These cases are matters of both civil and criminal law and proceedings can be instituted following a complaint by the patentee, a prosecutor, or the court itself.⁸¹

China's first Patent Law, enacted in 1984, was amended in both 1992 and 2000 to extend the scope of patent protection and to comply with international agreements and treaties.⁸² Unlike the United States' patent system, which gives patent rights to the first inventor, China follows a first-to-file system,⁸³ established under Article 9 of the Patent Law.⁸⁴ This means that patent rights are not necessarily granted to the first party to invent, but to the first party who files the invention; a different party often beats the inventor in this process.⁸⁵ Additionally, a foreign patent application must be filed through an authorized Chinese patent agent unless the filing person or firm has a business office in China.⁸⁶ This arguably makes patent filing more difficult for international competitors because they may have limited access to Chinese patent lawyers and information regarding current Chinese innovation.

Counterfeiters can be found guilty of violating Article 60 of China's Patent Law which states that a patentee can institute a legal proceeding against an infringer when that infringer "exploit[s a] patent without the authorization of the patentee."⁸⁷ Articles 57 through 62 address the legal proceedings and damages that follow such infringement.⁸⁸ These articles are discussed in greater detail below.

Because individual patents proscribe IP ownership of the active substances used to produce pharmaceuticals, the current Patent Law directly implicates the counterfeit market. Assuming that IP laws are adequately

⁷⁸ Ladas & Parry, LLP, Patent Litigation in China: Scope of Patent Protection, http://www.ladas.com/Litigation/ForeignPatentLitigation/ChinaPR_Patent_Litigation.html (last visited Nov. 11, 2007).

⁷⁹ The Supreme People's Court is the highest judicial organ in China. For more information on the Supreme People's Court, see ADB OECD Anti-Corruption Initiative for Asia-Pacific, Governmental Institutions, http://www1.oecd.org/daf/asiacom/countries/index_PRC.htm (last visited Nov. 15, 2007).

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

⁸³ *Id.*

⁸⁴ See Patent Law (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Aug. 25, 2000), art. 9, *translated in* LAWINFOCHINA (last visited Mar. 8, 2008) (P.R.C.) [hereinafter Patent Law].

⁸⁵ *Id.*

⁸⁶ See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

⁸⁷ Patent Law, *supra* note 84, art. 60.

⁸⁸ See *id.* arts. 58-67.

enforced, counterfeiters cannot appropriate protected inventions from legitimate inventors without legal repercussions. Specifically, the Patent Law provides infringers with a legal mechanism through which they can protect their IPR and recover damages when infringement occurs.

B. Pharmaceutical Counterfeiters in China Violate Chinese Trademark Law

Individuals or corporations may have a counterfeiting trademark claim if the product or trade dress—including the context of a label of the counterfeit product—is identical, or confusingly similar in appearance, to that of the authentic product.⁸⁹ The first Chinese Trademark Law was adopted in 1982 and revised in both 1993 and 2001.⁹⁰ The development of China's Trademark Law has amounted to a continuous effort to comply with requirements laid out in TRIPS.⁹¹ Specifically, over time, the Trademark Law extended registration to include collective marks, certification marks, and three-dimensional symbols.⁹² Also, the highest adjudicative power in cases of infringement was transferred from an administrative to a judicial mechanism.⁹³

Article 52 of the Trademark Law lists five specific acts that are considered trademark infringements.⁹⁴ Among other acts, these include selling goods that “bear a counterfeited registered trademark” and counterfeiting, making, or selling a registered trademark of another person without authorization or representation.⁹⁵

Like the Patent Law, China's Trademark Law requires all foreign companies to register their trademarks through a Chinese trademark agent and in a Chinese language version.⁹⁶ Also, as under its patent law, China has a first-to-file system for trademarks.⁹⁷ This system does not require evidence of prior use or ownership and thus allows third parties to register

⁸⁹ See Hilboldt, *supra* note 13, at 873.

⁹⁰ See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

⁹¹ Trademark Law (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 23, 1982, amended Oct. 27, 2001), art. 43, *translated in* Intellectual Property Rights In China, <http://www.chinaiprlaw.com/english/laws/laws11.htm> (last visited Mar. 1, 2008) (P.R.C.) [hereinafter Trademark Law].

⁹² See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

⁹³ Trademark Law, *supra* note 91.

⁹⁴ *Id.* art. 52.

⁹⁵ *Id.*

⁹⁶ Implementing Regulations of the Trademark Law (promulgated by St. Council, Aug. 3, 2002, effective Sept. 15, 2002), arts. 7-8, *translated in* <http://sbj.saic.gov.cn/english/show.asp?id=53&bm=flfg> (last visited Feb. 18, 2008) (P.R.C.).

⁹⁷ Trademark Law, *supra* note 91, art 29.

popular foreign marks.⁹⁸ Local third parties, called trademark pirates, can thus gain rights over foreign popular marks and reap significant profits from the foreign trademark holders' international popularity.⁹⁹ This is especially beneficial to pharmaceutical counterfeiters, who can take advantage of parties holding popular marks that are unable to find IP protection in China.

China has responded to this problem by promulgating laws to protect what are considered "well-known" marks.¹⁰⁰ Under Article 2 of the Provisions on the Determination and Protection of Well-Known Marks, "a well-known mark refers to a mark that is widely known to the relevant sectors of the public and enjoys a relatively high reputation in China."¹⁰¹ Article 14 of China's Trademark Law lays out five factors that the courts should consider when deciding whether something is or is not a well-known mark.¹⁰² Also, under Article 13 the legal owner of a mark that is not registered in China but is well-known there may bring a claim of opposition or cancellation against the previously registered mark.¹⁰³

As under patent law, trademark rights holders can utilize these provisions to protect themselves from infringement. Counterfeiters violating trademark rights create illegitimate drugs and package them using a well-known mark.¹⁰⁴ This allows them to sell the cheaply-produced product at the legitimate drug's market value, significantly reducing the trademark holder's profits. Trademark law provides a legal mechanism through which infringers can stop such infringement and recover damages for lost profits.

IV. THE CHINESE LEGAL SYSTEM DOES NOT EFFECTIVELY DETER PHARMACEUTICAL COUNTERFEITERS FROM ENTERING THE DRUG MARKET

Despite the existence of legal mechanisms for stopping IP infringement, enforcement of Chinese IP law is insufficient for several reasons. First, current Chinese IP law and methods of enforcement do not mandate strong enough punishments to deter counterfeiters from continuing

⁹⁸ See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

⁹⁹ See Wong, *supra* note 61, at 950.

¹⁰⁰ See Alisa Cahan, *China's Protection of Famous and Well-Known Marks: The Impact of China's Latest Trademark Law Reform on Infringement and Remedies*, 12 CARDOZO J. INT'L & COMP. L. 219, 222 (2004). There is currently no formal, universal definition for a "well-known" mark. *Id.* at 219.

¹⁰¹ Provisions on the Determination and Protection of Well-Known Marks (issued by the St. Admin. for Indus. and Commerce, Apr. 17, 2003), art. 2, *translated in* http://english.ipr.gov.cn/ipr/en/info/Article.jsp?a_no=2160&col_no=119&dir=200603 (last visited Mar. 1, 2008) (P.R.C.).

¹⁰² Trademark Law, *supra* note 91, art. 14.

¹⁰³ *Id.* art. 13. See also Wong, *supra* note 61, at 948.

¹⁰⁴ See generally Wong, *supra* note 61, at 950 (discussing IP infringement claims relating to well-known marks).

to infringe IPR.¹⁰⁵ Second, local autonomy has led to corruption in both the local government and the judiciary, causing an overall lack of enforcement of existing IP law. Third, inadequate judicial transparency and independence further hinders enforcement. Fourth, there are insufficient resources allocated to fighting drug counterfeiting in both the judicial and administrative sectors.

A. *Current Administrative, Civil, and Criminal Enforcement of IPR Does Not Deter Parties from Engaging in Counterfeiting*

The Patent and Trademark Laws, by their express terms, provide protection from IP infringement and thus pharmaceutical counterfeiting. In China, these laws are enforced either through an administrative mechanism or through adjudication, including both civil and criminal action.¹⁰⁶ However, it is arguable whether such laws effectively deter parties from engaging in pharmaceutical counterfeiting. According to general deterrence theory, individuals will engage in criminal activities if they do not have a rational reason to fear punishment.¹⁰⁷ Under this theory, parties who are aware of increased punishment will alter their decision-making process and may choose not to engage in a given crime.¹⁰⁸ This theory, applied to drug counterfeiters in China, supports the argument that parties will continue to engage in counterfeiting as long as they are not adequately deterred from doing so.

1. *The Administrative Mechanism Is Most Often Used to Enforce IPR but Is Inadequate to Fight Drug Counterfeiting*

The administrative mechanism is the most utilized method of dealing with the drug counterfeiting problem in China today.¹⁰⁹ Specifically, the trademark office under China's State Administration on Agency and Commerce ("SAIC") is responsible for the enforcement of trademark protection,¹¹⁰ whereas SIPO is responsible for enforcement of patent rights.¹¹¹

¹⁰⁵ See Iyengar, *supra* note 4.

¹⁰⁶ See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

¹⁰⁷ Robert Keel, Rational Choice and Deterrence Theory (July 14, 2005), <http://www.umsl.edu/~keelr/200/ratchoc.html>.

¹⁰⁸ *Id.*

¹⁰⁹ U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

¹¹⁰ See *id.*

¹¹¹ *Id.*

SIPO is responsible for granting all patents and administratively enforcing them in provisional offices.¹¹² This enforcement includes investigating, mediating, providing cease and desist orders, and imposing fines in infringement cases.¹¹³ Under Article 57 of the Patent Law, if infringement of a patent right occurs “the patentee or any interested party may either bring a lawsuit to the people’s court, or request the patent administrative department, for settlement.”¹¹⁴ The administrative authorities for patent affairs have the power to order the infringer to immediately cease any acts of infringement.¹¹⁵ Any party who is dissatisfied with such an order may, within 15 days of receiving notification, file a suit in the people’s court in accordance with Chinese Administrative Litigation Law.¹¹⁶ Under Article 62, there is a two-year statute of limitations for filing a patent infringement suit, beginning on the day the patentee or the interested parties become aware, or should have become aware, of the act of infringement.¹¹⁷ If a suit is filed within the statute of limitations, and if the circumstances constitute a crime, the person deemed responsible shall be investigated for criminal liability under Article 216 of the Criminal Law.¹¹⁸

Alternately, SAIC has authority over trademark registration, recognition of well-known marks, and enforcement of trademark protection.¹¹⁹ SAIC applies the Trademark Law to protect against IP infringement arising from drug counterfeiting.¹²⁰ Article 53 of China’s Trademark Law states that “the interested parties shall resolve the dispute through consultation,” and if they cannot do so, “the trademark registrant or interested party may institute legal proceedings in the [p]eople’s [c]ourt.”¹²¹ Both SIPO and SAIC have investigative power and the ability to render punishment when infringement is determined.¹²² Specifically, each can enjoin an infringer from continuing production, mandate the destruction of

¹¹² *Id.*

¹¹³ U.S. Embassy Beijing, China, IPR Toolkit: Patent, <http://beijing.usembassy-china.org.cn/iprpatent.html> (last visited Mar. 4, 2008).

¹¹⁴ Patent Law, *supra* note 84, art. 57.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*, art. 62.

¹¹⁸ *Id.*, art. 58. See Criminal Law (promulgated by the Standing Comm. Nat’l People’s Cong., Mar. 14, 1997, effective Oct. 1, 1997), arts. 213-20, *translated in* http://www.npc.gov.cn/englishnpc/Law/2007-12/13/content_1384075.htm (last visited Mar. 1, 2008) (P.R.C.) [hereinafter Criminal Law] (addressing “Crimes of Infringing on Intellectual Property Rights”).

¹¹⁹ See U.S. Dep’t. of Comm. Int. Trade Admin., *supra* note 7.

¹²⁰ *Id.*

¹²¹ Trademark Law, *supra* note 91, art. 53.

¹²² See U.S. Dep’t. of Comm. Int. Trade Admin., *supra* note 7.

infringing marks or products, impose fines, and remove machines used to produce counterfeit goods.¹²³

While these agencies may choose to pass cases along to the judicial sector for either civil or criminal action instead of dealing with them internally,¹²⁴ such judicial action is not often utilized due mainly to the reluctance of administrative authorities to forward cases to the criminal authorities.¹²⁵ Furthermore, infringees are also reluctant to bring an action directly to the judiciary for criminal investigation.¹²⁶ This reluctance partially results from influential Chinese cultural ideals centered on collective societal welfare.¹²⁷ Such emphasis on collective welfare results in a decrease in use of the adversarial system of litigation.¹²⁸ Also, both the concept of litigation and IP law are relatively new to the Chinese legal system, thus many parties do not choose this route due to their lack of knowledge or experience of the system.¹²⁹ For these reasons, most IP infringement cases remain in the administrative system.¹³⁰

Administrative agencies arguably do not effectively protect IPR holders. Though legally empowered to enforce decisions, administrative agencies cannot award compensation to the IPR holders in most cases.¹³¹ The harmed infringer, who may have suffered great financial harm due to the infringement, is therefore left without monetary redress. And, while agencies do have the power to fine the infringer and seize goods and equipment used in manufacturing infringing products,¹³² these mechanisms are not very effective due to the shortage of available financial resources and trained staff to carry out enforcement.¹³³ In China, local governments provide the financing necessary to run administrative agencies successfully.¹³⁴ However, these governments may be reluctant to provide adequate funding for IP enforcement because it is financially beneficial for them to allow pharmaceutical counterfeiting to flourish in the local

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ See Ritter, *supra* note 66.

¹²⁶ See U.S. Dep't. of Comm., Int. Trade Admin., *supra* note 7.

¹²⁷ See Wong, *supra* note 61, at 963. The Chinese are encouraged to understand their responsibilities and obligations to others in order to create a harmonious, non-confrontational society. *Id.*

¹²⁸ *Id.*

¹²⁹ See Iyengar, *supra* note 4.

¹³⁰ See Wong, *supra* note 61, at 964.

¹³¹ See U.S. Dep't. of Comm., Int. Trade Admin., *supra* note 7.

¹³² *Id.*

¹³³ See Wong, *supra* note 61, at 965. This resource deficit is partially attributable to the constant increase in the volume of patent and trademark applications, which consumes a large part of the agencies' time and resources. *Id.*

¹³⁴ See *id.* at 967.

economies.¹³⁵ Due to the lack of available resources and adequate enforcement, administrative bodies are not likely to effectively fight against IP infringement or to deter parties from entering into the counterfeit drug market.

2. *Civil Action Does Not Effectively Deter Drug Counterfeiters from Entering the Market*

Like the threat of administrative action, penalties incurred as a result of civil litigation are arguably not effective at deterring counterfeiters. In China, there has been a steady increase in private civil proceedings focused on IP infringement. For example, the number of civil IP cases initiated in Chinese courts grew from 5265 in 2001 to 7800 in 2002.¹³⁶ Still, despite the increased involvement of the judiciary in cases of IP infringement, there has been little impact on the production of counterfeit drugs in China. This is due largely to the fact that even when cases are tried, the resulting punishment is too insignificant to cause real deterrent effects.¹³⁷ Article 58 of the Patent Law restricts fines to no more than three times the infringer's income, and Article 60 indicates that either the losses suffered by the patentee or the infringer's profits should be used to calculate damages.¹³⁸ Further, under Article 56 of China's Trademark Law, the amount of damages for infringement is the profit the infringer has earned or the injury the infringer has suffered from that infringement, including the expenses spent by the infringer to stop the infringement.¹³⁹ Where this amount is difficult to determine, the people's court imposes an amount of damages not exceeding RMB 500,000 (approximately U.S. \$62,500).¹⁴⁰

These limitations likely protect infringers who could otherwise be saddled with very large damage payments depending on the method of calculation employed by the court. Furthermore, because the amount set under Article 56 is merely a maximum, the actual fine imposed is often much lower. For example, the average fine imposed on counterfeiters in

¹³⁵ *Id.*

¹³⁶ See Jiang Zhipei, Recent Developments in China's Judicial Protection of Intellectual Property Rights, Address at Temple University Law School (Aug. 18, 2008), available at <http://www.chinaiprlaw.com/english/forum/forum43.htm>.

¹³⁷ SPECIAL 301 REPORT, *supra* note 17, at 19.

¹³⁸ Patent Law, *supra* note 84, arts. 58, 60.

¹³⁹ Trademark Law, *supra* note 91, art. 56.

¹⁴⁰ *Id.* RMB 500,000 is not always the set cap if the amount is not difficult to determine and could in some cases be greater. *See id.*

2000 was \$794, and the average compensation to infringers was \$19.¹⁴¹ This amount is not even increased for mass production infringers who have the ability to earn colossal profits and cause massive harm to scores of people.¹⁴² In fact, because counterfeiters have the potential to gain enormous profits, such low penalties are often considered a mere fiscal speed bump in doing business and thus do not cause potential counterfeiters to change course.¹⁴³

In addition to the fact that such provisions regarding damages may leave the law ineffective in deterring future infringement, it is debatable whether the fines currently imposed under Chinese law satisfy the TRIPS deterrence requirement. Again, TRIPS does not provide specific guidelines for fines imposed on counterfeiters and therefore does not provide any binding international norms that member nations must follow when sanctioning counterfeiters. Article 45 of TRIPS requires that damages provide “adequate” compensation to the rights holder.¹⁴⁴ However, it does not clarify what remedy would meet this requirement. Under a typical case of IP infringement, the potential harm caused to a rights holder could include the loss of his or her entire business and all assets tied to such business. This type of damage is not likely to be remedied by providing compensation equal to the production costs and price of the genuine product. It could be argued that it is therefore not “adequate,” and thus that existing remedies under Chinese law are not in compliance with the requirements of TRIPS.

The problem of insufficient redress in cases of IP infringement is further complicated by the fact that civil cases are not adjudicated equally for all IP players. According to China’s Civil Procedure Act, civil cases are usually handled within six months from the filing date.¹⁴⁵ Yet foreign parties are not protected by this law and therefore their cases may take years to adjudicate.¹⁴⁶ During this time, thousands of counterfeit drugs could continue to circulate in the Chinese drug market, resulting in inadequate legal relief for an aggrieved foreign party.¹⁴⁷

¹⁴¹ See Chow, *supra* note 72 (describing the fines and compensation in all counterfeiting cases in 2000).

¹⁴² See Iyengar, *supra* note 4.

¹⁴³ Evelyn Iritani, *China Pressed Over Piracy; The U.S. Asks the World Trade Organization to Make the Asian Nation Prove It Is Taking Action to Stop Illegal Copying of Movies and Software*, L.A. TIMES, Oct. 27, 2005, at C1 (quoting John Greenagel, spokesman for the Semiconductor Industry Association).

¹⁴⁴ See TRIPS, *supra* note 67, art. 45.

¹⁴⁵ See Zhonglin He, *Enforcement of Intellectual Property Law in Post-WTO China*, British Chinese Law Association Seminar, July 25, 2002, available at http://www.chinaiprlaw.com/english/forum/forum40.htm#_ftnref1.

¹⁴⁶ *Id.*

¹⁴⁷ See Wong, *supra* note 61, at 968.

3. *Chinese Criminal Law Is Inadequate to Deter Pharmaceutical Counterfeiters*

Like its administrative and civil counterparts, Chinese criminal law is inadequate to deter IP infringement. Under TRIPS, all member countries are required to provide for criminal procedures and penalties in cases of pharmaceutical counterfeiting.¹⁴⁸ Even though China has formally complied with this provision, simply providing for the possibility of criminal prosecution does not ensure adequate enforcement. In 2000, only about one in five-hundred cases were referred from the administrative to the judicial authorities for criminal prosecution, and this number has not significantly increased over time.¹⁴⁹

Chinese criminal law is arguably insufficient to deter individuals from engaging in pharmaceutical counterfeiting. Article 213 of the Criminal Law deals with counterfeiting trademarks.¹⁵⁰ This provision is only utilized when, according to Article 59 of the Trademark Law, “the case is so serious as to constitute a crime.”¹⁵¹ Under Article 59, when a case is “serious enough,” criminal prosecution shall follow, in addition to compensation for the damages suffered by the infringer.¹⁵² The literal reading of this language implies that IP infringement and criminality can be mutually exclusive under the law.¹⁵³ The circular assertion that something which constitutes a serious crime is a crime arguably creates space for vast judicial discretion to decide whether or not a counterfeiter should face criminal liability.¹⁵⁴ This distinction can cause failures in the enforcement against counterfeiting because courts may refrain from imposing criminal sanctions due to the pressure they receive from local governments.¹⁵⁵

If the case is considered serious enough to constitute a crime, Article 213 and 216 of the Criminal Law may be applied.¹⁵⁶ The maximum allotted prison sentence under the Criminal Law is not more than three years when the “circumstances are serious.”¹⁵⁷ Under this law, it is up to the judge to decide what constitutes a “serious circumstance,” and because there is no

¹⁴⁸ See Pitts, *supra* note 20.

¹⁴⁹ See Chow, *supra* note 72.

¹⁵⁰ See Criminal Law, *supra* note 118, art. 213.

¹⁵¹ See Trademark Law, *supra* note 91, art. 59.

¹⁵² *Id.*

¹⁵³ See Kanji, *supra* note 51, at 1275.

¹⁵⁴ See *id.*

¹⁵⁵ SPECIAL 301 REPORT, *supra* note 17, at 19.

¹⁵⁶ Criminal Law, *supra* note 118, arts. 213, 216.

¹⁵⁷ *Id.* art. 216. See also *id.* art. 213 (mandating the same punishment “if the case is of a serious nature”).

minimum length of imprisonment mandated, the judge could arguably choose to give a minimal prison sentence or no prison sentence at all for counterfeit convictions.¹⁵⁸ The same maximum prison sentence is allotted under Article 214 for someone who knowingly sells merchandise under a counterfeit trademark and under Article 215 for someone who is forging, manufacturing, or selling without authority another's registered trademarks.¹⁵⁹ Similarly, under Article 216, a maximum of three years imprisonment is provided for an individual who "counterfeits other people's patents."¹⁶⁰ Again, there is judicial discretion as to which offense should incur this maximum sentence and how long the prison terms should run.

Armed with this discretion, judges may choose to impose very low sentences for patent-related counterfeiting. Further, even if a judge did wish to impose a higher sanction, he or she would be bound by the low cap of three years.¹⁶¹ In a very limited exception under Article 214, this time of imprisonment can be extended up to seven years for cases where there is a significantly large amount of sales.¹⁶² However, this exception is rarely utilized because judges tend to avoid holding that a huge sales volume has been produced or sold in reaction to pressure from local governments that want to protect their interests in the counterfeit drug market.¹⁶³ The resulting prison terms prescribed for counterfeiting crimes are frequently too low to deter parties from engaging in counterfeit drug production and sale.¹⁶⁴

Furthermore, even when judges do attempt to hand down harsher penalties for violations of IP law, they struggle to find and apply the appropriate law governing infringement.¹⁶⁵ Because local people's congresses have the power to promulgate new laws and regulations to address IPR, and there is no formal communication system between the various Chinese localities, the applicable law is often inconsistent and ambiguous.¹⁶⁶ This inconsistency arguably encourages counterfeiters to relocate to areas governed by less stringent laws, as they may receive better

¹⁵⁸ See Wong, *supra* note 61, at 969-70.

¹⁵⁹ See Criminal Law, *supra* note 118, arts. 214, 215. Note that under Article 214, cases "involving a large sales volume" carry a minimum term of imprisonment of three years and a maximum term of seven years and that the same term applies under Article 215 for "cases of an especially serious nature." *Id.*

¹⁶⁰ *Id.* art. 216.

¹⁶¹ *Id.* arts. 214, 215.

¹⁶² *Id.* art. 214. See also Kanji, *supra* note 51, at 1273.

¹⁶³ See IP Dragon, Reaction to Danwei Article About China's Ratification of WIPO's Internet Treaties, <http://ipdragon.blogspot.com/2007/06/reaction-to-danwei-article-about-chinas.html> (June 18, 2007).

¹⁶⁴ See Criminal Law, *supra* note 118, art. 213.

¹⁶⁵ See Chow, *supra* note 72.

¹⁶⁶ See Wong, *supra* note 61, at 971; see also Jessica Jiong Zhou, Note, *Trademark Law & Enforcement in China: A Transnational Perspective*, 20 WIS. INT'L L.J. 415, 435-36 (2002).

treatment from courts sitting in certain localities, which in turn likely drowns those courts in IP litigation. This problem has partially been alleviated with China's obligations under TRIPS, however significant variance in legal interpretation remains, making protection of IPR inconsistent.¹⁶⁷

B. Local Autonomy Has Led to Corruption and Strong Local Support for the Counterfeit Pharmaceutical Market

Due to the inconsistency and lack of enforcement of IP law, strengthening the current law alone would likely not be sufficient to deter the production of counterfeit drugs. Regardless of the remedies tied to the infringement of IPR, the final decision of which mark to protect or which patent right to uphold is left in the hands of subjective local courts and administrative agencies.¹⁶⁸ Therefore, in order to assess the effectiveness of amending current IP law it is important to consider the forces that influence the judiciary's decisions in cases of drug counterfeiting.

Insufficient enforcement of the law, caused by local protectionism of drug counterfeiting, has arguably decreased even the low deterrent effect that current legal mechanisms provide. Based on its actions and statements, the central government in China has indicated a dedication to the protection of IPR.¹⁶⁹ However, this central level authority is comprised mainly of legislative and policy-making bodies, while actual implementation and enforcement of law occurs at the local level.¹⁷⁰ In recent years, there has been an increased trend towards solidifying local autonomy in China.¹⁷¹ This exertion has resulted in localism—the emergence of administrative bureaucracy in regions across China.¹⁷² As a result, Beijing's central power has eroded due to the formation of regional concentrations of power.¹⁷³ Although these localities must report to the central Chinese government, they have developed significant independence and autonomy over their own geographic areas, developing their own mini-economies, laws, and government power.

The growth of localism seriously affected the stability of the counterfeit pharmaceutical market in China. Specifically, local autonomy

¹⁶⁷ See Evans, *supra* note 59, at 604.

¹⁶⁸ See Wong, *supra* note 61, at 964-76 (arguing that local protectionism, lacking judicial independence and enforcement, along with inadequate mandated punishment lead to inadequate enforcement of IPR).

¹⁶⁹ See Chow, *supra* note 72.

¹⁷⁰ *Id.*

¹⁷¹ See Evans, *supra* note 59, at 590.

¹⁷² See Wong, *supra* note 61, at 965.

¹⁷³ *Id.*

has led to the corruption of local officials, who may accept kickbacks and bribes in exchange for either ignoring the counterfeiting activity in their localities or becoming active participants in the counterfeit business themselves.¹⁷⁴ Many of these local officials significantly benefit from the financial benefits associated with counterfeiting and therefore have a strong incentive to support continued production.¹⁷⁵

Furthermore, local governments and communities also benefit indirectly from the counterfeit drug market. In many localities, counterfeiters significantly contribute to the local market through the use of transportation, restaurants, and hotels.¹⁷⁶ In some regions, the counterfeit market is so intertwined with the legitimate local market that it has become nearly impossible to distinguish the counterfeit from the legitimate businesses.¹⁷⁷ In such areas, shutting down counterfeit production might seriously impact the local economy due to reliance on the counterfeiters' financial investment in the area.¹⁷⁸ Over time, such localism has given both government and local businesses strong incentive to support the counterfeit drug market. This structure of support makes IPR enforcement difficult because the judiciary lacks adequate independence from local officials and therefore tends not to render decisions that significantly harm the local counterfeit market.¹⁷⁹

C. *The Lack of Judicial Transparency and Independence in China Exacerbates the Counterfeiting Problem*

In addition to the growth of localism in China, the lack of judicial independence in China significantly hampers IPR enforcement.¹⁸⁰ The Chinese Constitution grants the people's court power of independent adjudication;¹⁸¹ however, in practice, the courts are reliant on the Chinese government in many aspects.¹⁸² There is a growing relationship between the local courts and other components of the local political system which not only hinders judicial independence but has given rise to local

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *See* Chow, *supra* note 72.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *See* Wong, *supra* note 61, at 970.

¹⁸⁰ *Id.*

¹⁸¹ People's courts are the judicial organs of China and are made up of local courts, special people's courts, and the Supreme People's Courts. *See* China's Judicial System: People's Courts, Procuratorates, and Public Security, <http://www.olemiss.edu/courses/pol324/chnjudic.htm> (last visited Feb. 10, 2008).

¹⁸² *See* Wong, *supra* note 61, at 970.

protectionism.¹⁸³ In fact, many leaders of Chinese local governments view courts simply as “subordinate departments of the local government.”¹⁸⁴

Under such local protectionism, judges tend to bias their decisions in favor of parties supported by local committees or local people’s congresses.¹⁸⁵ Chinese judges are especially affected by this pressure because they do not have tenure and, therefore, are subject to loss of benefits or even removal if they render a verdict that is disfavored by the local government.¹⁸⁶ Additionally, local courts may suffer from significant funding reductions if they do not take government interests seriously.¹⁸⁷ This lack of independence has a significant impact on the prosecution of pharmaceutical counterfeiters.

This issue is magnified by the lack of transparency within the judiciary itself, and the great potential for judicial corruption. The status and salaries of judges are low.¹⁸⁸ Meanwhile, the large amounts of money and property at stake in disputes involving counterfeiting create an added risk of corruption.¹⁸⁹ This, coupled with the shortage of adequately trained judges and lawyers,¹⁹⁰ allows for the possibility of serious unethical or unprofessional conduct.¹⁹¹ Thus, judges may be more likely to take a bribe from a counterfeiter in exchange for a more favorable ruling in an infringer’s favor, adding to the levels of corruption revolving around the counterfeit market.

D. A Significant Shortage of Resources Available to Address IP Infringement in China Encourages Growth in Counterfeiting

Both the administrative and judicial spheres in China lack the resources necessary to impact pharmaceutical counterfeiting.¹⁹² The Chinese government is responsible for providing funding and other resources to fight against the production and sale of counterfeit drugs and has publicly announced its intention to increase such efforts.¹⁹³ However, there are insufficient funds, personnel, and government resources allocated to attack

¹⁸³ ALBERT HUNG-YEE CHEN, AN INTRODUCTION TO THE LEGAL SYSTEM OF THE PEOPLE’S REPUBLIC OF CHINA 153 (3d ed. 2004).

¹⁸⁴ *Id.* at 153-54.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 153-54, 157.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 157.

¹⁸⁹ *Id.* at 155.

¹⁹⁰ See Evans, *supra* note 59, at 593.

¹⁹¹ See CHEN, *supra* note 183, at 155.

¹⁹² See Ritter, *supra* note 66.

¹⁹³ See U.S. Chamber of Commerce, *supra* note 15, at 7; see also Wong, *supra* note 61, at 967.

the counterfeiting problem, and the current levels of resources are only likely to decline.

Again, the administrative mechanism of either SIPO or SAIC handles most cases of IP infringement in China.¹⁹⁴ However, these agencies are also responsible for determining whether IPR should be granted in the first place.¹⁹⁵ Due to the influx of parties seeking to obtain IPR, these organizations allocate a significant portion of their budgets and personnel to reading and reviewing patent and trademark applications and thus have limited resources remaining to handle the investigation and adjudication of infringement claims.

Absent increased funding for enforcement purposes, China's growing involvement in the IP market is likely to lead to further depletions in government resources. For example, SIPO is already experiencing a resource crunch due to a large increase in patent filings. A report produced by WIPO shows a 488% increase in patent applications in China since 1995.¹⁹⁶ More troubling are figures released in 2006 that reveal that more than 90% of Chinese companies have no experience with IPR and have never submitted a patent to SIPO.¹⁹⁷ As the trend towards protection of innovation grows in China, many of these companies may apply for IP protection to keep up with their competitors, causing SIPO to become overloaded and unable to handle patent infringement cases.¹⁹⁸ SAIC is likely to experience similar issues with the increase of trademark filings and the simultaneous growth of IP infringement claims.¹⁹⁹

Similar budget constraints exist in the judiciary. The courts are often unable to deal with counterfeiting actions effectively due to the lack of resources allocated for such adjudication. This resource crunch is further frustrated by judicial inefficiency caused by lack of training. IP law is relatively new in China and neither judges, prosecutors, nor defense counsel are properly trained to adjudicate cases of IP infringement.²⁰⁰ This arguably decreases the speed of adjudication and thus increases overall cost. Furthermore, as in the administrative sector, if IP infringement litigation becomes more frequent and the government does not increase the courts'

¹⁹⁴ SPECIAL 301 REPORT, *supra* note 17, at 19.

¹⁹⁵ See U.S. Dep't. of Comm. Int. Trade Admin., *supra* note 7.

¹⁹⁶ See Joff Wild, *IP Overload? Thompson Scientific 2007 Patent Focus Report: China*, KNOWLEDGELINK NEWSLETTER, Jan./Feb. 2007, <http://scientific.thomson.com/news/newsletter/2007-02/8361190/>.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ See Wong, *supra* note 61, at 966.

²⁰⁰ *Id.* at 971.

budgets, the judiciary will likely not be able to carry such a large load of cases, possibly causing infringers to suffer from additional losses during lengthy litigation.

V. CHINA SHOULD TAKE ADDITIONAL STEPS TO FIGHT COUNTERFEITING BY CLARIFYING EXISTING LAW AND FIGHTING CORRUPTION AT ITS SOURCE

As described above, many IP infringement cases currently remain to be tried in the administrative sector. Even when transferred to the judiciary, infringement is treated as a crime only if the presiding judge deems the case to be “serious” enough to warrant such penalties.²⁰¹ This discretion often leads to lenient enforcement because judges tend to avoid rendering harsh decisions due to internal corruption or as a reaction to pressure from local government officials seeking to protect their own stake in the counterfeit market.²⁰² Two main steps could be taken to improve the current counterfeiting situation in China. First, fines should be increased, and enforcement mechanisms should be strengthened to ensure future deterrence of IP infringement.²⁰³ Second, an agency should be created to monitor the judiciary and local government officials, investigate counterfeiting activities, and educate the public regarding the negative implications of counterfeiting.

A. *Chinese Laws Should Be Amended to Increase Fines and Prison Terms Imposed on Pharmaceutical Counterfeiters*

China’s ineffective battle against counterfeiting stems partially from the insufficient punishment described above. Specifically, the low maximum fines and imprisonment terms prescribed by civil and criminal laws are slight punishments when compared to the enormous profits a party can acquire through counterfeiting.²⁰⁴ These laws should therefore be amended to increase administrative and criminal sanctions to levels high enough to ensure that the risk of counterfeiting outweighs possible profits earned by the production or sale of counterfeit pharmaceuticals. As a matter of general deterrence, counterfeiters will rationally weigh this increased severity of punishment when deciding whether to enter the counterfeit market, and with more stringent punishment, many will be deterred from doing so.

²⁰¹ See Trademark Law, *supra* note 91, art. 59.

²⁰² See Wong, *supra* note 61, at 970.

²⁰³ See Hilboldt, *supra* note 13, at 890.

²⁰⁴ See Iyengar, *supra* note 4.

First, a specific provision should be added to both the Patent Law and the Trademark Law stating that producing or selling counterfeit drugs is a crime and will be tried as such.²⁰⁵ Classifying counterfeiting drugs as a crime would diminish judicial discretion in the determination of whether specific cases should be deemed criminal, because all counterfeiting cases would automatically be considered “serious” enough to constitute a crime.

Second, in order for a criminal classification of counterfeiting to result in significant deterrence, the fines and prison terms mandated for such crimes should be increased.²⁰⁶ If counterfeiters face increased fines and prolonged prison terms, they are less likely to enter the counterfeiting market and more likely to cease current production to avoid such punishment. Classifying acts of drug counterfeiting as a crime would arguably lead to increased judicial involvement in the enforcement of IPR, as all such criminal proceedings would be automatically transferred to the judicial branch.

In order to deal with this growing problem, the Chinese central government must make additional funds available to combat counterfeiting. Funding must not only be provided for adjudicatory proceedings, but also for the police, who must be properly trained in methods used to trace and effectively confiscate and destroy counterfeit drugs.²⁰⁷ In order to provide such funding, the Chinese government should create a fund comprised of the confiscated profits from convicted counterfeiters. A large portion of these profits would go to the infringer in the form of damages and/or to support victims’ healthcare costs, and a certain portion could be allocated amongst the various entities working to fight against pharmaceutical counterfeiting in order to fund their efforts.

B. A Designated Anti-Corruption Agency Could Decrease Corruption and Increase Enforcement

In order to protect IPR and decrease counterfeiting, China should address the problem of protectionism from its source at the local level. Although amending Chinese law and providing resources for judicial action are two important steps towards adequate IPR protection, levels of Chinese pharmaceutical counterfeiting will probably not diminish as long as local

²⁰⁵ PHARMACEUTICAL WORKING GROUP, EUROPEAN UNION CHAMBER OF COMMERCE IN CHINA, EUROPEAN BUSINESS IN CHINA POSITION PAPER, at 172, 179 (2004), available at <http://www.europeanchamber.com.cn/show/details.php?id=86> (follow “Pharmaceutical Position Paper 2004” hyperlink).

²⁰⁶ See Iyengar, *supra* note 4.

²⁰⁷ See U.S. Chamber of Commerce, *supra* note 15.

government officials bar effective adjudication and enforcement.²⁰⁸ Specifically, China should create an agency solely designed to fight the corruption associated with counterfeit pharmaceutical production and sale.

Currently, an anti-corruption agency—the Independent Commission Against Corruption (“ICAC”)—operates in Hong Kong. The ICAC is charged with fighting general corruption in Hong Kong.²⁰⁹ This agency could be used as a model for an anti-corruption agency targeting the pharmaceutical industry. The ICAC uses a three-prong approach consisting of deterrence, prevention, and education that has proven to be relatively successful at fighting some types of corruption in Hong Kong.²¹⁰ The ICAC can, after obtaining a court order, scrutinize bank accounts and execute search warrants, as well as run major prevention and education campaigns.²¹¹

Although the ICAC reveals China’s strong anti-corruption sentiment, it alone is inadequate to fight against corruption relating to pharmaceutical counterfeiting. Agents working at the ICAC do not have the requisite expertise on counterfeiting and IP laws to address the complex issues associated with the counterfeit market. Additionally, the ICAC’s powers do not reach beyond its local boundaries because it is located exclusively in Hong Kong, whereas pharmaceutical counterfeiting spreads across localities and borders. Furthermore, because corruption associated with drug counterfeiting is vast, the ICAC likely does not have adequate resources to attack the problem effectively. For these reasons, an anti-corruption agency targeted specifically at fighting corruption related to drug counterfeiting should be established in China.

Unlike the ICAC, a new anti-corruption agency should be established with multiple offices in different regions in order to address corruption at the local level effectively. Because counterfeiting-related corruption is unique in each locality, each local anti-corruption department should be made up of highly trained and experienced agents capable of tackling counterfeiting in that specific region. Each office should be required to report to a central location monitored by the national Chinese government to ensure that

²⁰⁸ See Wong, *supra* note 61, at 970.

²⁰⁹ Tony Kwok Man-wai, *Formulating an Effective Anti-Corruption Strategy—The Experience of Hong Kong ICAC*, in RESOURCE MATERIAL SERIES NO. 69, at 196 (U.N. Asia & Far E. Inst. for the Prevent. of Crime and Treatment of Offenders, 2006), http://www.unafei.or.jp/english/pdf/PDF_rms/no69/16_P196-201.pdf.

²¹⁰ *Id.* at 198.

²¹¹ See Karl Schoenberger, *Hong Kong’s Secret Weapon the Graft Busters at the ICAC Have Made the Colony One of the World’s Great Business Cities. Can They Still Thrive Under China?* FORTUNE MAGAZINE, Nov. 25, 1996, available at http://money.cnn.com/magazines/fortune/fortune_archive/1996/11/25/218710/index.htm.

employees at each locality do not become involved in local corruption themselves. The central office should then be required to report to the WTO, which would monitor compliance with TRIPS requirements. This would, in turn, likely lead to increased international confidence in Chinese IPR enforcement.

Similar to the ICAC's power to obtain warrants, this anti-corruption agency should be vested with investigative and auditing powers²¹² in order to ensure that local government officials, judges, and lawyers do not take bribes from counterfeit producers and sellers. Further, like the ICAC, this agency should educate the public on drug counterfeiting and should establish a public complaint system through which citizens can report incidents of counterfeiting.²¹³ Such efforts have proven to be successful in the ICAC's fight against corruption²¹⁴ and would arguably have a similar effect on the counterfeit-pharmaceutical industry.

VI. CONCLUSION

Although China has taken several important steps to gain the confidence of the international community, its current enforcement of IPR remains inadequate to deter individuals from entering the counterfeit pharmaceutical market. In order to improve enforcement, the Chinese government should amend its laws to include higher financial sanctions and longer prison terms to deter counterfeiters. It should also funnel more resources into the judicial sector so it can better deal with infringement actions. Simultaneously, China should attack corruption at the local level by setting up an agency targeted at corruption associated with pharmaceutical counterfeiting. Targeting local corruption and amending applicable law will allow for increased enforcement and, with time, will likely deter counterfeiters from entering the market.

²¹² The proposed anti-corruption agency could utilize China's National Audit Office to aid in auditing efforts if it becomes too burdensome for the agency to handle on its own. For general information on China's National Audit Office, see ADB OECD Anti-Corruption Initiative for Asia-Pacific, *supra* note 79 (summarizing the duties of the National Audit Office of the People's Republic of China).

²¹³ See Man-wai, *supra* note 209, at 199.

²¹⁴ See Schoenberger, *supra* note 211.