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Awaking the Sleeping Dragon: The Evolving Chinese Patent Laws and its Implications for Pharmaceutical Patents

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Rachel T. Wu

Abstract

Part I of this Comment will discuss the development of the Chinese IP system and discuss why it has been ineffective in protecting pharmaceutical patents by comparing it to the US patent system. Part II analyzes the third amendment to the Chinese patent law and how it protects patents, particularly pharmaceutical ones, and deters counterfeiters from infringing upon the patents. Part II also presents different views on the effectiveness of the third amendment to protect patents. Part III argues that even though the third amendment is a great leap forward, pharmaceutical counterfeiting will continue to happen if the local governments do not cooperate with the central government in enforcing patent protection laws.

COMMENT

AWAKING THE SLEEPING DRAGON: THE EVOLVING CHINESE PATENT LAW AND ITS IMPLICATIONS FOR PHARMACEUTICAL PATENTS

Rachel T. Wu *

INTRODUCTION

Deemed to be in her Golden Age, China seeks to be a major player in the global economy¹ and is determined to enter the global intellectual property (“IP”) market.² With global trade concerns pressuring international businesses to pursue intellectual property rights (“IPR”) and China’s own desire for recognition in the global IP market, China has continuously increased her efforts to strengthen her domestic IPR protection laws to conform to the World Trade Organization’s (“WTO”) more stringent requirements.³ Unfortunately, despite China’s

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1. See Wci Shi, *Incurable or Remediable? Clues to Undoing the Gordian Knot Tied by Intellectual Property Rights Enforcement in China*, 30 U. PA. INT’L L.J. 541, 542 (2008) (noting that China has a strong desire to become part of the global economy); see also Kim-Kwong Chan, *China’s Socioeconomic Changes and the Implications for the Religion-State Dynamic in China*, 2004 BYU L. REV. 325, 325 (stating that China has become an important player in the world economy).

2. See Dina Bronshtcin, Comment, *Counterfeit Pharmaceuticals in China: Could Changes Bring Stronger Protection for Intellectual Property Rights and Human Health?*, 17 PAC. RIM. L. & POL’Y J. 439, 445 (2008) (reporting that China is seeking to become a legitimate participant in the global intellectual property (“IP”) community); Shi, *supra* note 1, at 542 (explaining that Chinese IP rights legislation has stepped up efforts to bring her domestic laws into conformity with her World Trade Organization (“WTO”) commitments).

3. See Bronshtcin, *supra* note 2, at 447 (asserting that China has amended her IP laws numerous times to comply with international agreements); Warren Newberry, Note, *Copyright Reform in China: A “TRIPS” Much Shorter and Less Strange than Imagined?*, 35 CONN. L. REV. 1425, 1425 (2003) (explaining that China promulgated numerous amendments to her copyright laws when she prepared to join the WTO).

efforts to strengthen her IP protection laws, she has failed to enforce these laws.⁴ The United States Trade Representative (“USTR”) has identified China as having one of the least developed and least effective IP regimes in the world.⁵ China’s expansive patent docket illustrates her underdeveloped IP system: over 4000 new patent infringement cases were filed annually in China in 2007 and 2008.⁶

Piracy in China has cost IP owners worldwide an estimated US\$2.4 billion in 2007 alone.⁷ China continues to be one of the world’s largest producers of counterfeit goods, including films, music, software, and pharmaceuticals, the last of which might have the most harmful effects.⁸ In fact, China is one of the world’s biggest producers of counterfeit drugs.⁹ Counterfeit

4. See Donald P. Harris, *The Honeymoon Is Over: The U.S.-China WTO Intellectual Property Complaint*, 32 FORDHAM INT’L L.J. 96, 97 (2008) [hereinafter Harris, *Honeymoon*] (arguing that despite adopting and implementing strong substantive IP laws, China has failed to enforce these laws); Newberry, *supra* note 3 (claiming that China has not enforced the new reformed copyright laws to meet international standards).

5. See OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE [USTR], 2009 SPECIAL 301 REPORT (2009), available at <http://www.ustr.gov/sites/default/files/Full%20Version%20of%20the%202009%20SPECIAL%20301%20REPORT.pdf> (declaring that China’s intellectual property rights (“IPR”) enforcement regime remains ineffective); Kimberly N. Van Voorhis & Christie Yang, *Recent Developments in Patent Law Worldwide*, 997 P.L.I. PATENTS, COPYRIGHTS, TRADEMARKS, & LITERARY PROPERTY COURSE HANDBOOK SERIES, 405, 408 (2010) (stating that the USTR’s Priority List has China as having one of the least developed regimes).

6. See, e.g., Voorhis & Yang, *supra* note 5 (reporting that over 4000 patent infringement suits were filed in 2008); Tony Chen & Mark Cohen, *Real and Present Danger: Patent Litigation in China*, LAW 360, June 10, 2009, www.law360.com/articles/105112 (“Over 4,000 new patent infringement cases were filed with Chinese courts in each of 2007 and 2008.”); Qian Huang & Paul Devinsky, *China—Home and Away: The Next IP Powerhouse*, LAW 360, Oct. 21, 2009, http://www.mwe.com/info/pubs/law360_102109.pdf (explaining that China had the biggest patent docket in the world in 2006 and that there were more than 4000 patent infringement cases filed in 2007).

7. See Harris, *Honeymoon*, *supra* note 4, at 102; INTERNATIONAL INTELLECTUAL PROPERTY ALLIANCE, 2008 SPECIAL 301 RECOMMENDATION app. A, 1 (2008), available at www.iipa.com/pdf/2008SPEC301LOSSLEVEL.pdf (showing that the estimated losses due to Chinese piracy was US\$2.4 billion between 2006 and 2007).

8. See Shi, *supra* note 1, at 544 (stating that China is the largest producer of fake goods); see also Chris Buckley, *On Piracy, an Advocate for China’s Progress*, N.Y. TIMES, Oct. 4, 2005, available at <http://www.nytimes.com/2005/10/04/technology/04iht-IPRjudge.html> (stating that the US government warns against piracy of films, music, software, and medicine in China).

9. See Bronhstein, *supra* note 2, at 439; Maria Nelson et al., *Counterfeit Pharmaceuticals: A Worldwide Problem*, 96 TRADEMARK REP. 1068, 1089 (“China remains one of the world’s largest sources of drugs, both legitimate and counterfeit.”).

pharmaceuticals pose serious health and economic dangers.¹⁰ Previously, the penalties for counterfeit drugs were so minimal that they were seen as business costs with little, if any, deterrent effect.¹¹ The ineffectiveness of the Chinese patent law and the powerlessness of the central government to prevent patent infringement have frustrated international litigants.¹² The likelihood of winning a patent infringement suit against counterfeit pharmaceutical producers is questionable, and winning a patent infringement suit rarely stops counterfeiters from continuing to infringe upon the winners' patents.¹³ In addition, international pharmaceutical patent holders face the risk of having their patents invalidated upon petition by local Chinese pharmaceutical companies.¹⁴ Recent developments and changes to the Chinese patent law, however, might promise a brighter future for international patent litigants.¹⁵ With the third and most recent amendment to her patent law ("third amendment"), China may be on her way to developing an effective patent system.¹⁶ China's lack of enforcement of its amended patent law, however, might dim this promising glow.¹⁷

Part I of this Comment will discuss the development of the Chinese IP system and discuss why it has been ineffective in

10. See Bronhstein, *supra* note 2, at 442 (explaining that counterfeit drugs pose serious health and economic risks); Nelson et al., *supra* note 9, at 1072 (discussing the health and economic harms of counterfeit drugs). See generally Andrew Marshall, *Prescription for Murder*, 40 SMITHSONIAN 32 (2009) (discussing the deadly effects of counterfeit drugs).

11. See Bronshtcin, *supra* note 2, at 456 ("[S]uch low penalties are often considered a mere fiscal speed bump in doing business."); 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 ("[T]he penalties are often 'so light they just amount to a cost of doing business for those who infringe.'").

12. See Harris, *Honeymoon*, *supra* note 4, at 114–15 (explaining that the United States filed a WTO complaint against China because of her inadequate IPR protection); Iritani, *supra* note 11 (declaring that the USTR is facing increased pressure from US business community over the amount of piracy of movies and software in China).

13. See *supra* note 11 and accompanying text (stating that the penalties for infringement are so low that they are seen as a business expense).

14. See, e.g., *infra* note 137 and accompanying text (discussing how Chinese pharmaceutical companies tried to get Pfizer's Viagra patent invalidated).

15. See *infra* Part II.C (discussing how the third amendment to the Chinese patent law benefits international litigants).

16. See *infra* Part II.B (discussing the benefits of the third amendment).

17. See *infra* Part II.C.1 (explaining that the lack of enforcement casts doubt on the effectiveness of the third amendment on patent protection).

protecting pharmaceutical patents by comparing it to the US patent system. Part II analyzes the third amendment to the Chinese patent law and how it protects patents, particularly pharmaceutical ones, and deters counterfeiters from infringing upon the patents. Part II also presents different views on the effectiveness of the third amendment to protect patents. Part III argues that even though the third amendment is a great leap forward, pharmaceutical counterfeiting will continue to happen if the local governments do not cooperate with the central government in enforcing patent protection laws.

I. *THE STRUCTURE OF THE CHINESE PATENT LAW AND ITS PROTECTION OF PATENTS PRIOR TO THE THIRD AMENDMENT*

Compared with her 5000 years of history, China's IP system is relatively young.¹⁸ Historically, China was not particularly receptive to IP rights, but she recognized that a developed IP system was necessary to legitimize herself as a major participant in the global economy.¹⁹ China's IP system has remained remarkably different from that of the United States, which has caused tension between the two countries.²⁰ Part I is dedicated to discussing and analyzing China's IP system, specifically her patent law, and conveying why it is ineffective in protecting patents. Part I first discusses the development of IP law in China and presents the concerns that the United States has about China's IP laws and details the structure of the Chinese patent law system. Second, it discusses the difficulties that international litigants face when suing for patent infringement in China. Last, Part I analyzes how Chinese pharmaceutical companies are starting to use IP laws to their own advantage.

18. *See infra* notes 23–24 and accompanying text (stating that with the death of imperialism in China in the early twentieth century, the need for IPR was great and an IP law, albeit weak, was implemented in China).

19. *See infra* note 33 and accompanying text (articulating that Deng Xiaoping thought a comprehensive IP system would encourage investment from abroad).

20. *See infra* Part I.B (discussing the tension between the United States and China caused by the latter not meeting her WTO obligations); Part I.F (analyzing the differences between the Chinese and US patent laws).

A. *Historical Background and Development of IP in China*

China's underdeveloped IP system can be traced back to her strict adherence to Confucian principles of sharing and community commitment over individualism.²¹ Confucian beliefs and the lack of formal laws in imperial China severely hampered the development of IP rights.²² With the fall of imperial China and the birth of a republican China, the need for patent laws was inevitable.²³ The first substantive national patent law was enacted in 1912, but it offered little protection for patents and little assurance to international patent holders in the Chinese market.²⁴ China's weak IP system was nearly abolished when the Communist Party took over China in 1949²⁵ and instilled the importance of communal success while disregarding individualism.²⁶ All inventions and innovations belonged to the government, and as a result, property rights in patents were

21. See Alexander C. Chen, *Climbing the Great Wall: A Guide to Intellectual Property Enforcement in the People's Republic of China*, 25 AIPLA Q.J. 1, 9–10 (1997) (discussing how China's adherence to Confucianism and Taoism thwarted development of her IP system); Raymond M. Gabriel, Comment, *The Patent Revolution: Proposed Reforms in Chinese Intellectual Property Law, Policy, and Practice Are the Latest Step to Bolster Patent Protection in China*, 9 ASIAN-PAC. L. & POL'Y J. 323, 325–26 (2008) (explaining that the idea of IP is “alien to Chinese culture,” which is focused on Confucianism and the importance of communal success).

22. See Gabriel, *supra* note 21, at 326 (discussing that Confucian principles and “the absence of formal laws in Imperial China precipitated a lack of individual rights, especially in intellectual property”). See generally Peter K. Yu, *The Second Coming of Intellectual Property Rights in China* (Benjamin Cardozo School of Law Occasional Papers in Intellectual Property Law No. 11, 2002), available at <http://www.uschinalawyer.org/files/articles/2dcoming.pdf> (describing the factors that thwarted China from developing effective IP laws).

23. Gabriel, *supra* note 21, at 326 (articulating that with the ending of Imperial China, the need for IP laws became apparent); Yu, *supra* note 22, at 4–5 (discussing the need for IPR in China in the twentieth century).

24. See Gabriel, *supra* note 21, at 326–27 (stating that the 1912 patent law offered little protection); Yu, *supra* note 22, at 6 (claiming that the 1912 patent law was insufficient).

25. See Gabriel, *supra* note 21, at 326 (asserting that the rise of the Communist Party in 1949 created great obstacles for IPR); see also Yu, *supra* note 22, at 7 (articulating that the prospects of IP protection in China became “gloomier” when the Communists took power in 1949).

26. See Gabriel, *supra* note 21, at 327–28 (noting that when the Communists took power, they reinforced the importance of communal prosperity over individual rights); see also Yu, *supra* note 22, at 21 (“Under the socialist economic system, property belongs to the State and the people, rather than private owners.”).

completely abolished in 1963.²⁷ The Cultural Revolution²⁸ brought the development of the IP system to a complete stop.²⁹ The imprisonment of scientists, writers, and other intellectuals who advocated individualism dissuaded people from claiming individual rights to their ideas and inventions.³⁰ For the next decade, China lacked a formal legal system, as previous laws were renounced and local officials were allowed to influence the local laws and court rulings.³¹

When Deng Xiaoping succeeded Chairman Mao, he initiated an ambitious program of economic and legal development.³² Recognizing that the development and implementation of IP rights would attract foreign investment, Chairman Deng focused on the enactment of a workable patent system.³³ China joined the World Intellectual Property

27. PETER GANEA & THOMAS PATTLOCH, *INTELLECTUAL PROPERTY LAW IN CHINA* 3 (Christopher Heath ed., 2005); Gabriel, *supra* note 21, at 327–28.

28. The Cultural Revolution, which lasted from 1966 to 1976, was a movement inaugurated by Chairman Mao in an attempt to prevent the development of a bureaucratized Soviet style of communism. During the Cultural Revolution, Chairman Mao's government closed schools, persecuted Chinese teachers and other intellectuals, burned books, and facilitated mass relocations of intellectuals to the countryside. LOUISE CHIPLEY SLAVICEK, *THE CHINESE CULTURAL REVOLUTION* 8–11 (2010).

29. See Gabriel, *supra* note 21, at 327 (“[T]he Cultural Revolution and the destruction of China’s legal system resulted in the complete halt of the development of intellectual property laws.”); see also Geoffrey T. Willard, *An Examination of China’s Emerging Intellectual Property Regime: Historical Underpinnings, the Current System and Prospects for the Future*, 6 *IND. INT’L & COMP. L. REV.* 411, 417 (1996) (mentioning that the Cultural Revolution halted the development of the IP laws in China).

30. *C.f.* Gabriel, *supra* note 21, at 327–28 (“The antipathy of individual intellectual property rights to community rights was illustrated, at its extreme, by the imprisonment of scientists, writers, artists, lawyers, and intellectuals during the Cultural Revolution.”); Yu, *supra* note 22, at 19 (describing how the Chinese government persecuted scientists, writers, artists, lawyers, and intellectuals during the Cultural Revolution).

31. See Gabriel, *supra* note 21, at 328 (explaining that laws merely “implemented Party policy and changed” as Party leadership changed and that “local officials had . . . influence over the rule of law through the People’s Courts” and protected its local citizens); see also Robert Bejesky, *Investing in the Dragon: Managing the Patent Versus Trade Secret Protection Decision for the Multinational Corporation in China*, 11 *TULSA J. COMP. & INT’L L.* 439, 449 (describing how China is ruled by people, not laws, which has consequential implications for IP protection rights).

32. See Gabriel, *supra* note 21, at 328 (“When Deng Xiaoping resumed power . . . the Chinese government began an ambitious program of economic and legal reform.”); see also Willard, *supra* note 29, at 420–21 (describing Deng Xiaoping’s program for economic reform, which led to the creation of a comprehensive IP regime in China).

33. See Gabriel, *supra* note 21, at 328–29; see also GANEA & PATTLOCH, *supra* note 27, at 2–4 (describing how Deng Xiaoping thought a national patent system would encourage overseas investment).

Organization³⁴ (“WIPO”) in 1980.³⁵ In 1984, China enacted a patent law that contained basic provisions, such as the subject matter that patents can cover, how to file a patent, the examination process of patents, and how patents should be protected.³⁶ Nevertheless, it lacked the essential features necessary to make it an effective and successful system.³⁷ For example, the 1984 Chinese patent law excluded patents for inventions involving food, beverages, and pharmaceuticals.³⁸ The 1984 law was amended in 1992 to cover pharmaceutical patents, but it still offered little patent protection.³⁹ The Chinese patent law was subsequently amended in 2001 and again in 2008 in attempts to make it more comprehensive and effective.⁴⁰

For the past two decades, China has tried to improve her patent law, but the ever-expanding power and autonomy of local governments have thwarted these efforts.⁴¹ In 2001, as part of her

34. World Intellectual Property Organization (“WIPO”) is a specialized agency of the United Nations and promotes the protection of IP throughout the world through cooperation among member states and in collaboration with other international organizations. See *What is WIPO?*, WIPO, http://www.wipo.int/about-wipo/en/what_is_wipo.html (last visited Jan. 1, 2011).

35. See Bronshtcin, *supra* note 2, at 439–40 (“In 1980, China took initial significant steps to improve its IP climate when it joined [WIPO].”); Jordana Cornish, *Cracks in the Great Wall: Why China’s Copyright Law Has Failed to Prevent Piracy of American Movies within Its Borders*, 9 VAND. J. ENT. & TECH. L. 405, 414 (2006) (noting that China joined WIPO in 1980).

36. See generally Patent Law (promulgated by the Standing Comm. Nat’l People’s Cong., Mar. 12, 1984, effective Mar. 12, 1984) (Lawinfochina) (China).

37. See Gabriel, *supra* note 21, at 330; see also Averie K. Hanson & Jean E. Shimotake, *Recent Developments in Patent Rights for Pharmaceuticals in China and India*, 18 PACE INT’L L. REV. 303, 305–06 (2006).

38. See Gabriel, *supra* note 21, at 330; see also Hanson & Shimotake, *supra* note 37, at 305–06.

39. See Gabriel, *supra* note 21, at 331 (claiming that although the Chinese patent law was amended in 1992, it still did not offer adequate protection for patents); Yu, *supra* note 22, at 10 (arguing that the 1992 amendment to the Chinese patent law “was not enough, especially when it was not properly implemented”).

40. See *infra* Part II.A–B (discussing the second and third amendments and how they made the Chinese patent law more effective and comprehensive).

41. See Bronshtcin, *supra* note 2, at 439 (commenting that although the Chinese government has tried to improve its patent protection system, “the growing power and autonomy of local governments has complicated and exacerbated the problem [of infringement]”); see also Jessica C. Wong, *The Challenges Multinational Corporations Face in Protecting Their Well-Known Trademarks in China*, 31 BROOK. J. INT’L L. 937, 964–76 (2006) (arguing that local governmental protectionism, the lack of judicial independence and enforcement, and inadequate mandated punishment led to weak enforcement of IPR).

effort to tighten her IP law, China joined the WTO.⁴² Due to China's potential to quickly become an economic powerhouse, the United States and European WTO member states demanded that China have more obligations and fewer rights than other members of the WTO.⁴³ In addition, the member states substantially debated China's status as a developing country⁴⁴ because developing countries are afforded certain flexibilities and benefits.⁴⁵ China thus attempted to self-designate as a developing country,⁴⁶ but other members objected to this designation, claiming that China received more foreign direct investment than any other country and was the third-largest trading nation and fourth-largest economy in the world.⁴⁷ China ultimately acceded as both a developing and developed country (in IP matters, China acceded as a developed country).⁴⁸ China was required to implement IP laws immediately instead of being

42. See Gabriel, *supra* note 21, at 332 (asserting that upon joining the WTO, "China promised to bring its existing IP laws into closer alignment with the Trade-Related Aspects of International Property Rights (TRIPS) agreement," which resulted in the second amendment of the Chinese patent law); see also Harris, *Honeymoon*, *supra* note 4, at 108 (asserting that China agreed to accede to the WTO after fifteen years of negotiations).

43. See Marcia Don Harpaz, *China and the WTO: New Kid on the Developing Bloc?* 5 (Hebrew Univ. of Jerusalem, Research Paper No. 2-07, 2007), available at www.ssrn.com/abstractid=961768 (listing the reduced rights and increased obligations that China had compared to other WTO members).

44. See Harris, *Honeymoon*, *supra* note 4, at 110–11 (discussing the reasons China was seen as a developed country); see also Harpaz, *supra* note 43, at 11–12, 71 (discussing the debates that WTO state members had over whether China should be considered a developing country, being that she is the world's third-largest trader and fourth-largest economy).

45. See Harris, *Honeymoon*, *supra* note 4, at 109–10 (explaining that if China acceded as a developing country, she would be afforded the flexibilities and benefits that developing countries are typically given); see also Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 687 (2006) [hereinafter Harris, *Carrying*] (commenting that developing countries in the WTO are afforded more "flexibility in addressing social, economic, and political concerns").

46. See Harris, *Honeymoon*, *supra* note 4, at 110 (noting that China made numerous attempts to accede as a developing country); see also Harpaz, *supra* note 43, at 10 (asserting that China's formal application to the WTO stressed that she was a developing country).

47. See sources cited *supra* note 44.

48. See Harris, *Honeymoon*, *supra* note 4, at 111 (reporting that in some areas, China acceded as a developing country and in others, such as countervailing duties, she acceded as a developed country); see also Harpaz, *supra* note 43, at 14 (quoting China's chief negotiator during her accession to the WTO, saying that China will insist on undertaking obligations that are consistent with her status as a developing country); *id.* at 9–44 (discussing the details of China's accession to the WTO and her obligations).

given the five-year grace period afforded developing countries.⁴⁹ Much optimism surrounded China's accession, but disappointment and frustration lay ahead.⁵⁰

B. *China's Patent Law Structure*

China implemented a set of legal mechanisms to prevent patent infringement, but the enforcement of IP laws is insufficient. In China, either administrative or adjudicative mechanisms can be used to enforce IP laws through both civil and criminal suits.⁵¹ Such mechanisms, however, are often ineffective against pharmaceutical counterfeiting.⁵² The administrative mechanism is one method commonly used to handle pharmaceutical patent infringement cases.⁵³ The State Intellectual Property Office ("SIPO") is responsible for granting and enforcing patents.⁵⁴ Enforcement includes investigating, mediating, imposing fines, and providing cease-and-desist orders through provisional offices and agencies.⁵⁵ Patent holders can request an administrative investigation for possible infringement

49. See Protocol on the Accession of the People's Republic of China, pt. I, § 2(A)(2), WT/L/432 (Nov. 23, 2001) (mandating that China implement IP laws immediately at the central and local government levels); Harris, *Honeymoon*, *supra* note 4, at 112.

50. See Harris, *Honeymoon*, *supra* note 4, 113 (noting that optimism about China's IPR enforcement was misplaced); see also ANDREW MERTHA, *THE POLITICS OF PIRACY: INTELLECTUAL PROPERTY IN CONTEMPORARY CHINA* 202 (2005) (arguing that China's inability to deter future counterfeiters is a major sign of her lack of anti-counterfeiting enforcement).

51. See Bronshtein, *supra* note 2, at 452 ("In China, [IP] laws are enforced either through an administrative mechanism or through adjudication, including both civil and criminal action."). See generally *Intellectual Property Rights: Toolkit*, EMBASSY OF US: BEIJING, CHINA, http://beijing.usembassy-china.org.cn/protecting_ipr.html (last visited Jan. 1, 2011) [hereinafter *IPR Toolkit*] (discussing how the IPR enforcement system works in China).

52. See *infra* Part II.D (discussing why the administrative and adjudicative mechanisms are ineffective against deterring patent infringement).

53. See Bronshtein, *supra* note 2, at 452; see also *IPR Toolkit*, *supra* note 51 (stating that China's State Drug Administration handles counterfeit pharmaceutical cases).

54. See Bronshtein, *supra* note 2, at 453 (indicating that SIPO is responsible for enforcing patents and discussing the means it takes to enforce patents); see also *Intellectual Property Rights: Patent*, EMBASSY OF US: BEIJING, CHINA, <http://beijing.usembassy-china.org.cn/iprpatent.html> (last visited Jan. 24, 2011) [hereinafter *IPR: Patent*] (listing the responsibilities of SIPO).

55. See sources cited *supra* note 54 (listing the powers and responsibilities of SIPO).

activity by filing such a request in the local SIPO office.⁵⁶ Upon the proper finding, the patent administrative authority can order an infringer to cease immediately.⁵⁷ If an infringer does not agree with the order, he has fifteen days after receiving the order to file an appeal in court.⁵⁸ There is a two-year statute of limitations to file a patent infringement suit, and time starts when the patentee becomes aware of the patent infringement.⁵⁹ If suit is brought within the statute of limitations and the infringement is deemed criminal, the infringer would also be investigated for criminal liability.⁶⁰

SIPO also has the power to enjoin the infringer from manufacturing, order the destruction of the infringing products, and confiscate the machinery used to make the counterfeit goods.⁶¹ Often, however, infringers just receive a monetary penalty, which cannot be given to the patentees, thus leaving them without any compensation.⁶² In addition, many local SIPO offices lack the financial means and motivation to train staff to

56. See *IPR: Patent*, *supra* note 54 (explaining that requests for an investigation of potentially infringing behavior begins at SIPO office).

57. Patent Law (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Aug. 25, 2000) (Lawinfochina), art. 57 (China) [hereinafter 2000 Patent Law] ("Where the authorities for patent work considers the infringement well found, it has the power to order the infringer to stop infringement acts immediately.").

58. *Id.* ("In case the party concerned is not satisfied with the decision, he or it may, within 15 days from the receipt of the notification of the order, institutes [sic] legal proceedings in the people's court, according to the Administrative Procedure Law of the People's Republic of China.").

59. *Id.* art. 62 ("Prescription for instituting legal proceedings concerning the infringement of patent right is two years counted from the date on which the patentee or any interested party obtains or should have obtained knowledge of the infringing act.").

60. *Id.* art. 58 ("Where the infringement constitutes a crime, he shall be prosecuted for his criminal liability.").

61. See Bronshtcin, *supra* note 2, at 453–54; Gerald Hanc, *Intellectual Property and Innovation in China*, SCI. & TRADE POLY PROGRAM (Aug. 2008), http://gallery.ida.org/chinaforum/forum/ip_innovation.html ("SAIC [State Administration on Industry and Commerce] has the power to order that the sale of infringing items cease and to stop further infringement, order the destruction of infringing marks or products, impose fines, and remove machines used to produce counterfeit goods.").

62. Bronshtcin, *supra* note 2, at 454 (discussing that administrative agencies cannot award compensation to patent holders in most cases, leaving "[t]he harmed infringe, who may have suffered great financial harm due to the infringement, without any monetary redress"); Hanc, *supra* note 61 (indicating that some of "the disadvantages of the administrative process include the lack of [monetary] compensation" to the infringe); see also *IPR Toolkit*, *supra* note 51 (stating that administrative agencies cannot award compensation to an IPR holder).

enforce the cease-and-desist orders: local governments provide the financing for administrative agencies, and may be hesitant to provide such funding if pharmaceutical counterfeiting is a large part of the local economy.⁶³ Agencies are also reluctant to forward patent infringement cases to the criminal authorities because doing so runs counter to the local government's wishes.⁶⁴

Because of the complexity of patent infringement disputes, the adjudicative mechanism is used more often than the administrative mechanism.⁶⁵ There are four levels in China's judicial system: (1) the Basic People's Court; (2) the Intermediate People's Court; (3) the Higher People's Court; and (4) the Supreme People's Court.⁶⁶ The highest court, the Supreme People's Court, has assigned about fifty courts to be first-instance courts for adjudication of patent infringement.⁶⁷

63. Bronshtein, *supra* note 2, at 454 (asserting that the administrative mechanism is "not very effective due to the shortage of available financial resources and trained staff to carry out enforcement," mainly due to local government's reluctance to fund local SIPOs); Andrew Evans, *Taming the Counterfeit Dragon: The WTO, TRIPS and Chinese Amendments to Intellectual Property Laws*, 31 GA. J. INT'L COMP. L. 587, 591 (2003) (stating that local governments are often reluctant to provide funding to enable administrative agencies to operate because they benefit financially from the pirating and counterfeiting); *see also* Wong, *supra* note 41, at 965, 967 (illustrating that administrative enforcement efforts are hindered by a lack of funding from local government).

64. *See* Bronshtein, *supra* note 2, at 454 (articulating that administrative authorities are reluctant to forward IPR infringement cases to the criminal authorities); *see also* *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) (stating that patent infringement cases often are not tried for criminal liability, resulting in very few criminal sanctions).

65. *See* Hane, *supra* note 61 ("Patent disputes remain the most likely of intellectual property right disputes to be adjudicated, due in large part of their relative complexity."); *IPR: Patent*, *supra* note 54.

66. *See* Benjamin Bai et al., *What Multinational Companies Need to Know about Patent Invalidation and Patent Litigation in China*, 5 NW. J. INT'L TECH. & INTELL. PROP. 449, 457 (2007); Donald C. Clarke, *The Chinese Legal System*, GEO. WASH. U. L. SCH. (July 4, 2005), <http://docs.law.gwu.edu/facweb/dclarke/public/ChineseLegalSystem.html>.

67. *See* Bai et al., *supra* note 66, at 458 ("Because of the complexity of patent cases, the Supreme People's Court has designated about 50 courts (mostly Intermediate People's Courts) around the country to be first-instance courts for adjudication of patent infringement claims."); Cheng Young-Shun, Comment, *Juridical Protection of Intellectual Property in China*, 9 DUKE J. COMP. & INT'L L. 267, 271 (1998) ("The Supreme People's Court has assigned forty-three of the 400 Intermediate People's Courts in China to serve as courts of first instance for patent infringement cases.").

The method used to determine whether infringement has occurred is very basic.⁶⁸ There is no analog to a *Markman* hearing⁶⁹ for claim construction in China as there is in the United States; during trial, the analysis of the claim might last between half a day and several days.⁷⁰ Chinese courts have not developed sophisticated construction methods to guide the determination of infringement and cannot use case law as guidelines.⁷¹ In addition, “plaintiffs must collect and submit their own evidence to meet their burden of proof regarding . . . patent infringement and damages.”⁷² Chinese courts only accept evidence in its original form and will sometimes allow evidence obtained from previous administrative or preliminary injunction proceedings.⁷³ Certain evidence collected outside of China must be notarized in the originating country and then authenticated by the applicable Chinese embassy or consulate.⁷⁴

C. *The Tension and Distrust between the United States and China*

The United States gave China between 2001 and 2005 to develop and implement IP laws by not immediately filing a complaint with the WTO against China, despite the United

68. See *infra* notes 70–71 (discussing the simplicity of the adjudicative process of patent infringement cases in China).

69. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (holding that before a patent infringement case goes to a jury, the judge must construe, as matter of law, the claims of the relevant patent); see also Richard Raysman & Peter Brown, ‘*Markman*’ *Hearings and Computer Terms*, N.Y. L.J., Feb. 10, 2004, at 1 (describing *Markman* hearings as pre-trial proceedings “in which the trial judge is presented with evidence to construe the key terms in the patent claims”).

70. Benjamin Bai et al., *How to Litigate Patents in China*, 5 CHINA IP FOCUS 3, 5 (2007) (“There is no US-style, pre-trial *Markman* hearing for claim construction. Claim construction and infringement analysis occur at trial, which might last between half a day and a couple of days.”).

71. See Bai et al., *supra* note 66, at 461 (commenting that Chinese courts have yet to elaborate on canons of construction to determine infringement and that China is not a common-law jurisdiction); Laurie Self & Jason Ma, *Amending China’s Trademark Law: A Discussion of the Possible Changes to Trademark Law in China*, 218 TRADEMARK WORLD 18, 20 (2009) (mentioning that case law in China is not binding on lower courts).

72. Bai et al., *supra* note 66, at 459; see also Shun, *supra* note 67, at 269 (“[T]he complainant can file criminal suit in his own name if he presents sufficient evidence that the defendant had infringed his intellectual property rights.”).

73. Civil Procedure Law (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 28, 2007) (Lawinfochina), art. 68 (China) [hereinafter Chinese Civil Procedure Law] (stating that all documents must be in their original form to be submitted into evidence).

74. See *id.* art. 67.

States' apparent belief that the Chinese IP laws were unacceptable.⁷⁵ The United States became so wary and frustrated by China's lack of progress that in 2006 it established the China Enforcement Task Force to prepare WTO cases against China.⁷⁶ The Chinese Supreme People's Court and Supreme People's Procuratorate tried to ameliorate some of the frustration and dissatisfaction by issuing a decision that permitted a lower standard for IPR prosecution and increased the penalties for infringement, but the United States was still not satisfied.⁷⁷ The United States complained that China's criminal law did not sufficiently deter would-be infringers and did not order the disposal of infringing goods.⁷⁸

Pressured by the United States, China promised to conform her existing IP laws to the guidelines laid out in the WTO's Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreement.⁷⁹ The TRIPS agreement, however, only established the minimum baseline for IP protection and is not self-executing.⁸⁰ The TRIPS agreement also allowed the member

75. See Harris, *Honeymoon*, *supra* note 4, at 114 (mentioning that between 2001 and 2005, the United States gave China time to implement its WTO IP obligations, but China was slow to do so). See generally USTR, *Fact Sheet: WTO Case Challenging Weaknesses in China's Legal Regime for Protection, Enforcement of Copyrights, Trademarks*, U.S. FED. NEWS, Apr. 9, 2007, available at 2007 WLNR 6947235 (discussing the weaknesses of the Chinese IP system).

76. See Harris, *Honeymoon*, *supra* note 4, at 114; see also USTR, U.S.-CHINA TRADE RELATIONS: ENTERING A NEW PHASE OF GREATER ACCOUNTABILITY AND ENFORCEMENT 5 (2006), available at <http://www.ustr.gov/sites/default/files/Top-to-Bottom%20Review%20FINAL.pdf> (asserting that the United States attempted to ensure China's compliance with trade obligations by establishing a China Enforcement Task Force).

77. See Harris, *Honeymoon*, *supra* note 4, at 114 ("The United States considered this a good but inadequate step."); see also USTR, *supra* note 75 (recognizing the importance of the decision, but arguing that a major safe harbor was still available for counterfeiters).

78. See Harris, *Honeymoon*, *supra* note 4, at 115 (listing the complaints that the United States had alleged against China in its WTO complaint); Requests for Consultations by the United States, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/1 (Apr. 10, 2007) [hereinafter Consultations] (discussing all the complaints the United States had against China).

79. See Gabriel, *supra* note 21, at 332 (mentioning that China promised to align its patent laws more closely with the TRIPS agreement); Harris, *Honeymoon*, *supra* note 4, at 101 (discussing how the United States pushed for China to become a party to the TRIPS agreement).

80. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 3 n.3, 108 Stat. 4809, 869 U.N.T.S. 299 [hereinafter TRIPS Agreement] ("For the purposes of Article 3 and 4, 'protection' shall include matters affecting the availability,

states some flexibility in interpreting and implementing the agreement into their domestic legislation.⁸¹

In sum, China's IP laws have created a troubled relationship with the United States, which has grown increasingly suspicious of China's devotion to IP protection. The United States has continuously complained that China is not fulfilling her WTO obligations, but to no avail.

D. *China's Ineffective Penalties for Patent Infringement*

Before the third amendment to the Chinese patent law, civil penalties were also ineffective in deterring counterfeiters⁸²—courts could not impose damages exceeding CN¥500,000 (about US\$62,500).⁸³ The number of patent infringement civil proceedings, however, has steadily risen in China.⁸⁴ Chinese patent law set the ceiling for fines at three times the infringer's income,⁸⁵ and both the patentee's losses and infringer's profits

acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.”); *see also* Jacob A. Schroeder, *So Long as You Live Under My Roof, You'll Live by . . . Whose Rules?: Ending the Extraterritorial Application of Patent Law*, 18 *TEX. INTELL. PROP. L.J.* 55, 66 (2009) (stating that the TRIPS agreement provides its members some flexibility to implement their TRIPS agreement obligations).

81. *See* TRIPS Agreement, *supra* note 80, art. 1 (“Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”); *see also* Schroeder, *supra* note 80, at 66 (“The TRIPS agreement establishes minimum, baseline intellectual property protection.”).

82. *See supra* note 11 and accompanying text (mentioning that the fines are so low that they are just seen as a business cost).

83. *See* Trademark Law (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 23, 1982, amended Oct. 27, 2001) (*Lawinfochina*), art. 56 (China), [hereinafter Trademark Law] (“If . . . it is difficult to determine the losses suffered by the infringed due to the infringement[,] the people's court shall determine a compensation of 500,000 Yuan or below according to the circumstances of the infringing acts.”); *infra* note 172 (discussing the maximum fines that the Chinese patent law allowed after the third amendment).

84. *See* Bronshtein, *supra* note 2, at 455 (asserting that the number of civil proceedings dealing with IP infringement have been increasing); *see also* Jiang Zhipci, *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> (citing that the number of IP infringement civil cases has increased from 5200 in 2001 to 7800 in 2002).

85. 2000 Patent Law, *supra* note 57, art. 58 (providing that an infringer “may be coupled with a fine of no more than 3 times of his illegal income”).

are used to calculate damages.⁸⁶ The amount of damages also includes the expenses incurred by the patentee to stop the infringement.⁸⁷ While these are the maximum limits for fines, actual fines given in infringement cases are much lower, averaging below US\$800.⁸⁸ The courts do not take into account the ability of infringers to make gigantic profits on the counterfeit products nor the severity of harm that the product can cause to the public.⁸⁹

Even though China had implemented criminal procedure and penalties for IP infringement, she rarely enforced them.⁹⁰ In 2002, the courts had convicted infringers in less than one percent of the counterfeiting cases that administrative agencies had handled.⁹¹ Under Chinese laws, criminal prosecution will only be pursued “[i]f the circumstances are serious.”⁹² This statutory language gives courts wide discretion, which is sometimes abused, especially when local governments pressure judges to overlook the infringement.⁹³ Furthermore, even when

86. *Id.* art. 60 (“The amount of damages for infringing a patent right shall be calculated according to the losses suffered by the patentee or the profits gained by the infringer out of the infringement.”).

87. Trademark Law, *supra* note 83, art. 56 (providing that the infringer should be compensated for “the losses suffered . . . due to the infringement during the period of being infringed, including the reasonable expenses paid by the infringer to stop the infringing acts”).

88. 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, 109th Cong. (May 16, 2005) (statement of Daniel Chow, Professor, Ohio State University Michael E. Moritz College of Law), available at <http://www.cccc.gov/pages/roundtables/051605/Chow.php?PHPSESSID=d10701156c60debc015f3a19a5733202> [hereinafter Chow] (reporting that the average fine was US\$794 in 2000).

89. See Bronshicin, *supra* note 2, at 456; Jayanthi Iyengar, *Intellectual Property Piracy Rocks China Boat*, ASIA TIMES, Sept. 16, 2004, <http://www.atimes.com/atimes/China/FI16Ad07.html> (arguing that piracy in China flourished because of high returns and low punishment).

90. See *supra* note 64 (discussing how infringers are rarely criminally prosecuted).

91. See Chow, *supra* note 88 (“[I]n 2000, only about 1 in every 500 infringement cases were referred to judicial authorities for criminal prosecutions.”); Timothy P. Trainer, *The Fight against Trademark Counterfeiting*, CHINA BUS. REV., Nov.–Dec. 2002, at 20, 22 (“Between January and May 2002, the criminal tribunals of the People’s Courts convicted only 187 trademark infringers. This number represents far less than one percent of the tens of thousands of counterfeiting cases that the administrative authorities dealt with during the same period.”).

92. 2000 Patent Law, *supra* note 57, art. 64.

93. See USTR, 2006 SPECIAL 301 REPORT (2006), available at http://ustradep.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asst_upload_file473_9336.pdf (“China has thus maintained a legal ‘safe harbor’ that

patent infringers are found criminally liable, the maximum sentence permitted under the law is three years if “circumstances are serious” and between three and seven years if the infringement is of “a more serious nature.”⁹⁴ This language again allows the courts to use a wide range of discretion.⁹⁵ In addition, because local legislatures have the power to enact local IPR protection rules and do not communicate with each other about these rules, rules are inconsistent among localities.⁹⁶

E. *The Differences between the Chinese and US Patent Law*

The US patent law system differs remarkably from China’s and many other nations’ systems.⁹⁷ Several major differences between US and Chinese patent law include patent priority, grace periods, prior user rights, and the best-mode requirement.⁹⁸ Regarding patent priority, the United States

protects a large group of commercial infringers and operates to deprive the criminal enforcement authorities of needed information regarding the sources of counterfeit and pirated goods.”); Bronshtein, *supra* note 2, at 457 (arguing that the flexibility of the statutory language and the pressure that judges receive from local governments prevents them from imposing criminal sanctions); *see also* Omari Kanji, Note, *Paper Dragon: Inadequate Protection of Intellectual Property Rights in China*, 27 MICH. J. INT’L L. 1261, 1275 (2006) (“Article 59 allows prosecution of pirates where the case is ‘so serious as to constitute a crime,’ which simultaneously implies that IP piracy and criminality can be mutually exclusive and fails to establish a threshold for criminality.”).

94. Criminal Law Provisions of Intellectual Property Crime (promulgated by the Standing Comm. Nat’l People’s Cong., July 1, 1979, amended Mar. 14, 1997) (Lawinfochina), arts. 215–16 (China) [hereinafter Criminal Law].

95. *See supra* note 93 and accompanying text (explaining that courts are afforded discretion in deciding whether infringers should be held criminally liable).

96. *See* Bronshtein, *supra* note 2, at 458 (“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.”); Jessica Jiong Zhou, *Trademark Law & Enforcement in China: A Transnational Perspective*, 20 WIS. INT’L L.J. 415, 435–36 (2002) (arguing that China is very decentralized, leading to confusion about applicable laws and lax enforcement at the local level).

97. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL 32996, PATENT REFORM: INNOVATION ISSUES 8 (2005) (claiming that there are several notable distinctions between the US patent law and those of her leading trading partners); Ryan M. Corbett, Note, *Harmonization of U.S. and Foreign Patent Law and H.R. 2795: The Patent Reform Act of 2005*, 18 FLA. J. INT’L L. 717, 718 (2006) (illustrating that there are several aspects of US patent law that differ from the patent laws of many other nations).

98. *See* Corbett, *supra* note 97, at 719–22 (2006) (detailing the five major differences between foreign and US patent law); Robert R. Willis, *International Patent Law: Should United States and Foreign Patent Laws Be Uniform? An Analysis of the Benefits, Problems, and Barriers*, 10 N.C. J. L. & TECH. 283, 293 (2009).

employs a first-to-invent system,⁹⁹ while China, like most other nations, uses a first-to-file system.¹⁰⁰ In the United States, when two independent inventors file patent applications for the same invention at the same time, the patent will be granted to the applicant who can prove he was the first to invent the device.¹⁰¹ In contrast, a first-to-file system grants the patent to the first person to file for the patent.¹⁰² Unlike courts in first-to-invent systems, courts that operate in a first-to-file system do not need to address problems of burden of proof or examine supporting evidence to determine which litigant has priority because ownership of a patent is controlled by the date of filing.¹⁰³

Pursuant to the United States Code, an applicant is prohibited from obtaining a patent on an invention that was described in a printed publication within or outside of the United States, or was in public use or on sale in the United States more than one year prior to the date of the filing in the United States.¹⁰⁴ The US patent system provides inventors with a grace period during which they are allowed to publicize, and even commercialize, their inventions without surrendering their rights to patent their inventions.¹⁰⁵ In China, a publication or disclosure of an invention or similar invention results in the rejection of the patent.¹⁰⁶ For example, GlaxoSmithKline was forced to abandon one of the claims for its anti-diabetic drug Avandia because

99. See Peter A. Jackman, *Adoption of a First-to-File Patent System: A Proposal*, 26 U. BALT. L. REV. 67, 67 (1997); see also Willis, *supra* note 98, at 293.

100. 2000 Patent Law, *supra* note 57, art. 9 ("Where two or more applicants file applications for patent for the identical invention-creation, the patent right shall be granted to the applicant whose application was filed first.")

101. See Corbett, *supra* note 97, at 719; Willis, *supra* note 98, at 293.

102. See Corbett, *supra* note 97, at 723; Willis, *supra* note 98, at 296.

103. See Willis, *supra* note 98, at 296; see also Jackman, *supra* note 99, at 74 (reasoning that because courts in first-to-file systems only have to worry about the date of filing, they do not normally have to look at any prior dates of conception).

104. 35 U.S.C. § 102(b) (2002) ("A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in the public use or on sale in this country, more than one year prior to the date of application for patent in the United States.")

105. See *id.*; see also Willis, *supra* note 98, at 296 ("A grace period provides a limited period of time to the applicant in which he or she may introduce the patent to the public or commercial spotlight without forfeiting the right to obtain a patent.")

106. See 2000 Patent Law, *supra* note 57, art. 23 ("Any design for which patent right may be granted must not be identical with or similar to any design which, before the date of filing, has been publicly disclosed in publications in the country or abroad or has been publicly used in the country.")

Chinese plaintiffs sought to invalidate the patent, claiming the patent covered information that had been previously published and was available to the public.¹⁰⁷

Litigants in a first-to-file system can use prior-user rights as a defense in limited situations.¹⁰⁸ For example, in some circumstances, prior users can assert, as a defense, a previous commercial use of the patent or a significant preparation for such a use before the filing date of the application.¹⁰⁹ Prior-user rights do not function as a defense in first-to-invent systems because they allow the first inventor to invalidate patents that were issued to later inventors.¹¹⁰ In first-to-file systems that allow prior users defenses, prior users will be allowed a limited use of the patent if they can establish sufficient pre-filing activity.¹¹¹

The United States has also adopted the best-mode requirement, which mandates that an applicant disclose the best method for executing the invention.¹¹² Hence, the inventor

107. 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, 18 (2006); see also Phelim Kyne & Leslie Chang, *Glaxo Gives Up Chinese Patent Amid Drug Makers' Challenge*, *WALL ST. J.*, Aug. 19, 2004, at B6 (reporting that GlaxoSmithKline decided to abandon a defense of its formulation for rosiglitazone because three Chinese makers of generic drugs claimed that some of the novel elements of Avandia covered by GlaxoSmithKline's patent had already been published in the public domain before GlaxoSmithKline filed the patent).

108. Willis, *supra* note 98, at 297; see Vito J. DeBari, Note, *International Harmonization of Patent Law: A Proposed Solution to the United States' First-to-File Debate*, 16 *FORDHAM INT'L L.J.* 687, 700 (1993).

109. Willis, *supra* note 98, at 297; see DeBari, *supra* note 108, at 700.

110. See DeBari, *supra* note 108, at 700–01 (“In a first-to-file system, however, priority is based on the filing of the patent application. Thus, without a prior user right, a prior user is unable to continue using the independently developed invention if someone else obtains a patent for the same invention.”); Willis, *supra* note 98, at 297 (“[A] prior user rights provision attempts to provide an equitable solution for first-to-file situations that the first-to-invent system naturally provides for.”).

111. DeBari, *supra* note 108, at 701 (“With a prior user right, if prior users can establish sufficient pre-filing activity, they will be permitted to continue such use despite the presence of another's patent, subject to specific limitations on the extent of that use.”); see ADVISORY COMM'N ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE 11 (1992) (proposing that the United States adopt a first-to-file system in which a limited prior user right should apply, which “right should be cast as a limited equitable defense to a claim of infringement that would be available only to those who had used or made substantial preparation for use of the patented invention prior to the filing date of a subsequently issued patent.”).

112. 35 U.S.C. § 112 (2006) (“The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention.”); see Willis, *supra* note 98, at 298 (“The ‘best mode requirement’ mandates that an applicant must disclose the best method contemplated for carrying out the invention.”).

cannot submit an inferior version of his invention and keep the best version to himself.¹¹³ Patents can be invalidated if they do not comply with the best-mode requirement.¹¹⁴ To determine whether this requirement is fulfilled, US courts use a two-pronged test that asks: (1) whether at the time of filing, the inventor actually had a best mode in mind, and (2) if he did, whether the written description disclosed the best mode in a way that someone skilled in the ordinary art could replicate the best mode.¹¹⁵ If the inventor does not know of a best mode at the time of filing, he is exempted from disclosing this information and the patent will be valid.¹¹⁶

The Chinese standards are much stricter. Under the Chinese patent law, the applicant is required to disclose enough information to enable a person skilled in the relevant field of technology to understand and exploit the invention accordingly and requires the patent to describe “in detail the optimally selected mode contemplated by the applicant for carrying out the invention or utility model.”¹¹⁷ SIPO most likely invalidated Pfizer’s Viagra patent because it disclosed sildenafil citrate along with eight other ingredients as the “most preferred ingredients” and it was not descriptive enough under the Chinese patent

113. Willis, *supra* note 98, at 298; *see* Corbett, *supra* note 98, at 722 (“Allowing the inventor to disclose an inferior version of the invention while keeping the best embodiment a secret[] goes against the disclosure goals of patent law.”).

114. *See* 35 U.S.C. § 112 (asserting that a patent application’s written specification “shall set forth the best mode contemplated by the inventor of carrying out his invention”); *see also* Jeanne C. Fromer, *The Compatibility of Patent Law and the Internet*, 78 *FORDHAM L. REV.* 2783, 2788 (“Patents are granted after successfully undergoing an examination by the Patent and Trademark Office to ascertain that an invention meets patentability conditions and its description in the patent application satisfies specified disclosure requirements of a written description, enablement, and best mode.”).

115. *See, e.g.*, *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 Fed. Appx. 974, 977 (Fed. Cir. 2008) (applying the two-pronged test); *Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001).

116. *See* *Benger Labs. Ltd. v. R.K. Laros Co.*, 209 F. Supp. 639, 644 (E.D. Pa. 1962) (holding that a failure to disclose the best method does not invalidate a patent if the patent holder did not know it or appreciate that it was the best method); *see also* *Engelhard Industries, Inc. v. Sel-Rex Corp.*, 253 F. Supp. 832, 837 (D.N.J. 1966) (citing *Benger Labs*, 209 F. Supp. at 644).

117. Implementing Regulations of the Patent Law of the People’s Republic of China (promulgated by the State Council of the People’s Republic of China, June 15, 2001, amended Jan. 9, 2010), *available at* http://www.ccpit-patent.com.cn/nting_Regulations_Patent_Law_China.htm.

law.¹¹⁸ US law does not mandate a detailed description of the optimally selected model.¹¹⁹

Another difference is that the United States Code permits judges to award the prevailing party attorney's fees in exceptional cases.¹²⁰ Exceptional cases have been limited to those in which a party is guilty of litigation misconduct, which includes vexatious, unjustified, and otherwise bad litigation, a frivolous suit, or willful infringement.¹²¹ The Chinese patent law, however, does not punish parties for conducting bad faith litigation.¹²² Thus, it is possible for some bad faith actors to apply for patents for prior arts or designs and immediately sue others for infringing their patents once they obtain them.¹²³

118. See Andrews, *supra* note 107, at 27. See generally Lizhu Zheng, *Invalidation Decision of Viagra Patent Revoked in China*, CASRIP NEWSL., Spring/Summer 2006, available at <http://www.law.washington.edu/Casrip/Newsletter/default.aspx?year=2006&article=newsv13i2/heng> (describing the reasons why the Viagra patent was invalidated).

119. 37 C.F.R. § 1.71(b) (2005). This statute expands upon the "best mode" requirement laid out in 35 U.S.C. § 112 by stating:

The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation of principle whenever applicable.

Id.

120. 35 U.S.C. § 285 (2010) ("The court in exceptional cases may award reasonable attorney fees to prevailing party.").

121. See *Epcon Gas System, Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1035 (6th Cir. 2002) (holding that an attorney's failure to conduct a thorough investigation into an infringement claim, basing all allegations on rumors, is insufficient to deem the case exceptional, and that a reward of attorney's fees should not be granted); *Hoffman-La Roche Inc. v. Invadmed Inc.*, 213 F.3d 1359, 1365 (3d Cir. 2000) (holding that a case in which the plaintiff suspected infringement and made reasonable efforts to substantiate his claims does not fall under the exceptional case rule); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (4th Cir. 1989) (holding that a defendant's litigation strategy of pleading irrelevant defenses that required lengthy defense and repeated violation of temporary injunctions constituted vexatious litigation).

122. See Xiaoqing Feng, *The Interaction between Enhancing the Capacity for Independent Innovation and Patent Protection: A Perspective on the Third Amendment to the Patent Law of the P.R. China*, 9 U. PITT. J. TECH. L. & POL'Y 1, 126-27 (2009) ("[S]ome illegal actors will make use of [the patent system] to apply for patent for the knowingly prior art or design, and immediately accuse others of infringing upon his patent rights after he has obtained patent right.").

123. See *id.*

F. *The Difficulties that International Litigants Face when Pursuing a Patent Infringement Case in China*

The Chinese patent law advises parties to try to solve patent disputes through negotiation before pursuing legal or administrative proceedings.¹²⁴ Because Chinese courts do not mandate or provide for a formal discovery process, some lawyers opt for the use of the administrative process to establish infringement, appreciative of its speed and usefulness in gathering evidence.¹²⁵ As mentioned above, however, administrative agencies lack funding and impose low fines for infringers.¹²⁶ In addition, they often refuse to initiate an investigation due to local protectionism and corruption.¹²⁷ International litigants who collect their evidence in their home country must get the evidence notarized, and translated before it is admissible in court.¹²⁸ Another factor dissuading filing civil actions is the unequal treatment of the parties.¹²⁹ Civil cases are supposed to be handled within six months of the filing date.¹³⁰ International parties, however, are not protected by this law, and

124. 2000 Patent Law, *supra* note 57, art. 57 (“The authorities for patent work may, upon the request of the parties concerned, mediate on the damages concerned. If mediation does not work, the parties concerned may lodge a lawsuit with the people’s court according to the Civil Procedure Law of the People’s Republic of China.”).

125. See Bai et al., *supra* note 66, at 459 (“Because there is no U.S.-style discovery process in China, plaintiffs must collect and submit their own evidence.”); *The Patent Law of the People’s Republic of China*, LADAS & PARRY LLP, <http://www.ladas.com/Patents/PatentPractice/ChinaPatentLaw/index.html> (last visited Jan. 1, 2011) (reporting that China has no discovery procedure in which documents must be given to the opposing side).

126. See *supra* notes 62–63 and accompanying text (arguing that because of local corruption, SIPO often does not have the funding to enforce the patent law and is pressured into imposing low fines for patent infringement).

127. See Bronshtein, *supra* note 2, at 459 (“Insufficient enforcement of the law, caused by the local governmental protectionism of drug counterfeiting, has arguably decreased even the low deterrent effect that current legal mechanisms provide.”); see also Wong, *supra* note 41, at 964–72 (claiming that local governmental protectionism along with inadequate penalties have led to poor IPR enforcement).

128. Chinese Civil Procedure Law, *supra* note 73, art. 68–68.

129. See, e.g., Wong, *supra* note 41, at 968 (mentioning that patent infringement cases filed by foreign litigants are adjudicated much more slowly than those filed by domestic litigants).

130. Chinese Civil Procedure Law, *supra* note 73, art. 135 (“A people’s court shall complete the adjudication of a case to which ordinary procedure is applied within six months after the case is accepted.”).

it might be several years before their cases are adjudicated.¹³¹ Even if international parties initiate a suit, they face many difficulties partly because the problems of protectionism and corruption also contribute to the unlikelihood of international parties winning a patent infringement case in Chinese courts.

G. *Recent Developments in China's Pharmaceutical Industry Are Changing the Perspective on IP Law*

PricewaterhouseCoopers estimated that China's pharmaceutical industry was worth US\$28.2 billion in 2000;¹³² the industry netted sales of US\$7.5 billion in 2004.¹³³ In recent years, China's pharmaceutical industry has continuously grown in both profits and size, largely due to the central government's funding of the industry's development and research.¹³⁴

With increasing funding and profits, Chinese pharmaceutical companies that were originally built to pirate patented pharmaceuticals are beginning to manipulate the IP laws to their own advantage.¹³⁵ For example, during the beginning of the new millennium, Chinese plaintiffs petitioned SIPO to invalidate several US pharmaceutical giants' drug patents. On September 19, 2001, SIPO granted Pfizer a patent

131. See Wong, *supra* note 41, at 968 (noting that the six-month time frame is not adhered to for international litigants); see, e.g., Geoffrey A. Fowler, *Starbucks Wins China Court Case over Trademark*, WALL ST. J., Jan. 3, 2006, <http://www.corpwatch.org/article.php?id=13005> (noting that Starbucks won a trademark infringement case in 2006 that it filed in 2003).

132. See Andrews, *supra* note 107, at 8 (citing PricewaterhouseCoopers' estimate that the Chinese pharmaceutical industry was worth US\$28.2 billion in 2000).

133. TED C. FISHMAN, CHINA, INC.: HOW THE RISE OF THE NEXT SUPERPOWER CHALLENGES AMERICA AND THE WORLD 222 (2005).

134. See Andrews, *supra* note 107, at 8-9 ("The central government is currently putting money into the pharmaceutical industry, specifically to encourage domestic research and development."); Alex S. Dai, *The Push for Pharmaceuticals*, INSIGHT, May 2009, at 31 ("China's pharmaceutical R&D industry has grown rapidly over the past few years as a result of China's lower cost base, a liberal research and investment environment, government support and incentives."); see also *China's Pharmaceutical Industry Gets Major Push*, CHINA.ORG, Apr. 24, 2002, available at <http://www.china.org.cn/english/2002/Apr/31451.htm> (stating that the Chinese government plans to invest around US\$120 million in researching and developing drugs from 2002 until 2005).

135. Andrews, *supra* note 107, at 9 (arguing that the counterfeiters are beginning to use IP laws as a strategic tool); see also Peter K. Yu, *Viagra's Upside*, IP LAW & BUS., Oct. 2004 (arguing that the Pfizer lawsuit marks the first time that Chinese companies took a legal route to challenge a patent issued to a major international company and that Chinese companies are learning how to use the IP laws to their benefit).

for Viagra's active ingredient.¹³⁶ Almost immediately after SIPO granted the patent, however, a dozen Chinese pharmaceutical companies and individuals filed petitions with SIPO to have the patent invalidated, claiming that it failed to provide adequate disclosure under Article 26 of the Chinese patent law and that it lacked novelty as required by Article 22.¹³⁷ On July 7, 2004, the Patent Reexamination Board decided to invalidate the Viagra patent, claiming that it did not meet the disclosure requirement.¹³⁸ Pfizer appealed the Patent Reexamination Board's decision to the Beijing First Immediate People's Court on September 28, 2004.¹³⁹ In June 2006, the Beijing First Immediate People's Court reversed the invalidation and remanded the case to SIPO for further determinations.¹⁴⁰ The Chinese pharmaceutical companies then appealed to the Beijing High People's Court, which upheld the Beijing First Intermediate Court's decision on September 7, 2007.¹⁴¹

136. See Andrews, *supra* note 107, at 11; Zheng, *supra* note 118.

137. See Andrews, *supra* note 107, at 12–13 (explaining that the basis for the challenge of Pfizer's patent was that the patent did not meet the novelty requirement under the Chinese patent law); see also Richard A. Castellano, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA 283, 311–12 (detailing the reasons for SIPO's invalidation of Pfizer's patent).

138. See sources cited *supra* note 118 (noting some of the reasons for the Patent Reexamination Board's decision to invalidate the Viagra patent).

139. Huirui Aierlan Yaopin Gongsi Su Zhonghua Renmin Gonghe Guojia Zhishichanquan Ju Zhuanli Fushen Weiyuanhui (辉瑞爱尔兰药品公司诉中华人民共和国国家知识产权局专利复审委员会一审行政判决书) [Pfizer Ireland Pharmaceuticals v. Republic of China State Intellectual Property Office Board of Patent Appeals First Instance Administrative Judgment] (Beijing Interm. People's Ct. June 2006), available at <http://bjgy.chinacourt.org/public/paperview.php?id=26344> [hereinafter Pfizer Ireland Pharmaceuticals]; see Andrews, *supra* note 107, at 2, n.6; Emma Barraclough, *Pfizer Victorious over Viagra in China*, MANAGING INTELL. PROP., Oct. 2007, at 10.

140. See Pfizer Ireland Pharmaceuticals, *supra* note 139 (reversing the Patent Reexamination Board's decision and remanding the case for further proceedings); see also Barraclough, *supra* note 139 (stating that the Beijing First Immediate People's Court overturned the Patent Reexamination Board decision); Tony Chen, *Beijing High Court Upholds Viagra Patent in China*, IP PERSPECTIVES, Fall/Winter 2007, at 30.

141. Tianjinshi Lianxiang Yaoye Youxian Gongshi Dengyu Huirui Aierlan Yaopin Gongsi deng Zhuanli Wuxiao Xingzheng Jiufen an Er Shen Xingzheng Panjue Shu (天津市联想药业有限公司等与辉瑞爱尔兰药品公司等专利无效行政纠纷案二审行政判决书) [Tianjin Pharmaceutical Co., Ltd. v. Second Instance the Patent Invalid Chief Administrative Judgment], (Beijing High People's Ct. Sept. 7, 2007), available at <http://bjgy.chinacourt.org/public/paperview.php?id=26967>; see Barraclough, *supra* note 139; Chen, *supra* note 140, at 32 (indicating that ten of the thirteen petitioners appealed the Pfizer case to the Beijing High People's Court, which ultimately upheld the lower court's decision).

Another target was GlaxoSmithKline, which placed its popular anti-diabetic drug Avandia into the Chinese market between 2000 and 2001.¹⁴² A group of Chinese drug producers filed petitions to invalidate GlaxoSmithKline's patent on rosiglitazone, one of the three patented active ingredients in Avandia.¹⁴³ GlaxoSmithKline eventually decided to voluntarily abandon its patent on rosiglitazone,¹⁴⁴ perhaps because it witnessed the results of the Pfizer cases and was contemptuous of the Chinese patent law.¹⁴⁵

Chinese pharmaceutical companies started to use IP laws as a mechanism to invalidate international companies' patents,¹⁴⁶ causing greater frustration for international investors who must not only prevent their patents from being infringed, but must also protect them from being invalidated.¹⁴⁷ International parties

142. See Bai et al., *supra* note 66, at 450 (noting that Avandia entered the Chinese market in the second half of 2000); Jia Hepeng, *Pharmaceutical Giant Gives Up Medicine Patent*, CHINA BUS. WEEKLY (Beijing), Aug. 26, 2004, http://www.chinadaily.com.cn/english/doc/2004-08/26/content_369176.htm (claiming that Avandia was launched in China in 2001).

143. See *supra* note 107 and accompanying text (stating that several Chinese drug companies tried to get GlaxoSmithKline's patent invalidated, claiming that it did not meet the novelty requirement).

144. See sources cited *supra* note 142 (claiming that GlaxoSmithKline voluntarily abandoned its rosiglitazone patent).

145. See Hepeng, *supra* note 142 (citing a drug patent expert with Beijing-based NTD Intellectual Property Agency's statements that GlaxoSmithKline's withdrawal might have been caused by its fear of seeing the Pfizer's Viagra invalidated); see also Andrews, *supra* note 107, at 18 ("[S]ome foreign companies began to express their less-than-optimistic views of the Chinese intellectual property environment through their actions. Most notably, GlaxoSmithKline abandoned a defense of its formulation patent for rosiglitazone, the key ingredient of its popular Type 2 diabetes drug Avandia.").

146. See, e.g., *supra* notes 142-45 and accompanying text (describing how GlaxoSmithKline abandoned its Avandia patent after several Chinese pharmaceutical companies attempted to get it invalidated).

147. Bai et al., *supra* note 66, at 449 (explaining that multinational companies are both suing for patent infringement and being sued to get their patents invalidated); Ram Deshpande & Alok Aggarwal, *Patently Speaking: Failure to Heed IP in China Can Be Costly*, MAG. OF INTELL. PROP. & TECH., July 15, 2009, available at <http://www.ipfrontline.com/printtemplate.asp?id=23218> ("Litigation statistics indicate that Chinese companies are increasingly becoming more aggressive with patent enforcement and non-Chinese companies operating in China have started to feel the heat."); see also Hepeng, *supra* note 142 (citing Guo Xiaodong as suggesting that domestic pharmaceutical firms may be tempted to copy international companies' pharmaceutical compounds by looking for loopholes in their Chinese patents).

have increasingly become involved in patent litigation as both defendants and plaintiffs.¹⁴⁸

China's IP protection scheme has changed significantly since the days of strict adherence to Confucian principles. Over the years, due to her own desire become a major participant in the global economy and pressure by other countries, China has tried to improve her IP laws by amending them. The 2000 Chinese patent law, however, was deficient in many ways and did not offer enough protection for patents. The United States became wary of China's ineffective patent law, and filed a WTO complaint against China in 2005, claiming that China did not meet her WTO obligations. China, in turn, tried to strengthen her IP laws, but the United States saw China's attempts as inadequate. International companies also became disdainful of the Chinese patent law when Chinese companies started using the law to invalidate international companies' patents. In addition, international, especially American, litigants face a number of challenges when litigating a patent infringement suit in China. As a result of all the complaints, China became increasingly cognizant of the need to amend her patent law.

II. *THIRD AMENDMENT TO THE CHINESE PATENT LAW: PROMISING GLOW OR DISAPPOINTING FLICKER?*

Complaints about the Chinese patent law did not go unheard. In 2008, China amended her patent law for the third time, hoping that the third amendment would address all the previous concerns. Whether the third amendment will resolve the earlier deficiencies is still uncertain and remains a point of disagreement among scholars.

Section A of this Part delineates the changes that the first and second amendments made to the Chinese patent law and outlines the problems and deficiencies in the Chinese patent law prior to the third amendment. Section B discusses the third amendment's major effects on the Chinese patent law and compares the state of Chinese patent law before and after the

148. See Bai et al., *supra* note 66, at 449 ("While foreign parties have brought fewer than 5% of these cases so far, they have increasingly become involved in the litigation, both as defendants and plaintiffs."); Deshpande & Aggarwal, *supra* note 147 ("In 1,139 of [the 23,518 IP litigations filed in China in 2008], a foreign company was either the plaintiff or the defendant, which is more than triple the number in 2006).")

third amendment. Section C sets forth the different scholarly arguments about the anticipated effects of the third amendment on patent protection and litigation in China. It will first articulate the positive anticipated effects, with an emphasis on the particular sections of the third amendment that are predicted to create these improvements. Last, this Part discusses scholarly arguments that anticipate the third amendment's negative effects and predicts its inability to reform patent protection and patent litigation in China, as well as the particular sections that will be most impactful.

A. *The First and Second Amendments to the Chinese Patent Law*

Since its enactment in 1984, the Chinese patent law has undergone three amendments.¹⁴⁹ First, in 1992, it was amended to expand patentable subject matter to include pharmaceuticals and extend the patent terms for invention patents from fifteen to twenty years.¹⁵⁰ The second amendment in 2000 was made in anticipation of China's accession to the WTO¹⁵¹ and included a number of provisions that bolstered the protection and enforcement of patents in China.¹⁵² Various parts of the second amendment focused on assisting non-Chinese entities in filing patents in China.¹⁵³ Unfortunately, despite the changes brought by the second amendment, the Chinese patent law was still

149. See *infra* note 150 and accompanying text and Part II.A–B (detailing the changes that the three amendments made to the Chinese patent law).

150. Xia-Yun Gao, *An Introduction to Administrative Protection for Pharmaceuticals*, Comment, 9 DUKE J. COMP. & INT'L L. 259, 259 (1998) (stating that in 1992, administrative protection for pharmaceutical products was provided); Wei-Ning Yang & Andrew Y. Yen, *The Dragon Gets New IP Claws: The Latest Amendments to the Chinese Patent Law*, INTELL. PROP. & TECH. L.J., May 2009, at 18, 18 (mentioning that the 1992 amendment allowed pharmaceuticals to fall under patentable subject matter).

151. Yang & Yen, *supra* note 150, at 19; see also Jiwen Chen, *Better Patent Law for International Commitment—The Amendment of Chinese Patent Law*, 1 RICH. J. GLOBAL L. & BUS. 61, 61 (2001).

152. See Chen, *supra* note 151, at 61 (asserting that the second amendment brought upon three major changes: new judicial and administrative protection, improved application procedures, and simplified enforcement procedures); see also Yang & Yen, *supra* note 150, at 19 (“The 2000 amendment incorporates various provisions to strengthen protection and enforcement of patent rights in China.”).

153. See Chen, *supra* note 151, at 67–69 (detailing the provisions that simplify the patent application process for international entities); see also Yang & Yen, *supra* note 150, at 19 (“Various provisions of the 2000 amendment also aim to facilitate the patent application process for foreign entities in China.”).

deficient in many aspects.¹⁵⁴ The 2000 Chinese patent law was still unclear in many areas and open to interpretation.¹⁵⁵ The ambiguity of the 2000 Chinese patent law allowed bad faith applicants to file for patents for prior arts or inventions and bring frivolous infringement suits without any repercussions.¹⁵⁶ These deficiencies led to inadequate patent protection and accentuated the need for the Chinese patent law to be amended for a third time.

B. *The Changes Brought by the Third Amendment*

On June 5, 2008, China's State Council issued the National Intellectual Property Strategy Outline ("Outline"), which laid out a plan to help China establish higher efficiency in the creation, utilization, protection, and administration of IP rights by 2020.¹⁵⁷ The Outline emphasized that China needs to establish a comprehensive IP system, promote creation and utilization of IP, increase IP protection, and prevent the abuse of IP rights.¹⁵⁸ The third amendment, finalized in December 2008, increased monetary damages against patent infringers and provided additional administrative and judicial tools to better protect patents.¹⁵⁹ It prohibits two types of patent law violations: acts of "passing off" patents and patent infringement.¹⁶⁰

154. See *supra* Part I.C–D (describing the ineffectiveness of Chinese patent law prior to the third amendment in deterring patent infringement).

155. See *supra* Part I (discussing the problems and loopholes of the 2000 Chinese patent law).

156. See *supra* note 123 and accompanying text (arguing that because the 2000 patent law does not require utility and design patents to go through substantial examination, it was possible for some bad actors to apply for a patent for a prior art or design and immediately accuse others of infringing his patent).

157. See Guo Jia Zhi Hui Chan Quan Zhan Lue Gang Yao (国家知识产权战略纲要) [National Intellectual Property Strategy Outline] (promulgated by St. Council China), Issuc No. 17, Serial No. 1268, ST. COUNCIL GAZ. (June 20, 2008), available at http://www.gov.cn/gongbao/content/2008/content_1018942.htm.

158. See *id.* (listing the four goals and detailing how to achieve them).

159. See Yang & Yen, *supra* note 150, at 21 (asserting that the third amendment aspired to enhance the protection of patent rights in China by increasing monetary damages and providing administrative and judicial tools to improve enforcement of patent rights). See generally *The Third Amendment to Patent Law to Increase the Strength of Patent Protection on Six Measures*, GUIZHOU PROVINCE INTELL. PROP. BUREAU (2009), available at <http://www.gzsipo.gov.cn/ywdt/display.asp?id=784> [hereinafter *Patent Protection on Six Measures*].

160. See *Patent Protection on Six Measures*, *supra* note 159 (asserting that the third amendment will provide clearer terms of what constitutes patent infringement); Yang &

The “passing off” of patents occurs when a person deceives others into believing someone else’s patent is his own or that he holds the patent to an unpatented product or process.¹⁶¹ Specifically, passing off patents includes manufacturing or selling generic products with a patent marking; continuing to manufacture or sell a product or process whose patent has been invalidated; advertising or promoting an unpatented technology as a patented technology; and forging or transforming any patent certificate, patent document or patent application.¹⁶² The third amendment drastically increased the civil fines for passing off patents. The third amendment provides that, in addition to taking the income earned from acts of passing off patents, the Patent Administrative Department¹⁶³ has the right to impose a fine up to four times the illegal income of the violator in contrast to the previous maximum of three times the illegal earnings.¹⁶⁴ The third amendment provides that, absent any illegal earnings, the Patent Administrative Department may fine the violator up to CN¥200,000 (about US\$29,200), compared to the previous cap of CN¥50,000 (about US\$7300).¹⁶⁵

Yen, *supra* note 150, at 21 (stating that the third amendment to the Chinese patent law would specify the acts of patent counterfeiting offenses).

161. *See* Patent Law (promulgated by the Standing Comm. Nat’l People’s Cong., Mar. 12, 1984, 3d amend., Dec. 27, 2008) (Lawinfochina), art. 69 (China) [hereinafter 2008 Patent Law] (stating that a person is not infringing when, after the sale of a patented product was imported by the patentee or with authorization of the patentee, or was directly obtained by the using the patented process, he uses, offers to sell, or sells that product); Yang & Yen, *supra* note 150, at 21 (clarifying what constitutes passing off patents).

162. *See* The People’s Government of Henan Province, Administrative Guidance Issued Regarding the Punishment for Passing Off Patents and Passing Off Products or Processes (2007), *available at* <http://www.henan.gov.cn/bsfw/system/2007/09/06/010040254.shtml>.

163. *See* 2008 Patent Law, *supra* note 161, art. 3 (“The patent administrative department of the State Council shall be responsible for the administration of the patent work throughout China, uniformly accept and examine applications for patents, and grant patents in accordance with the law.”).

164. *Compare* 2008 Patent Law, *supra* note 161, art. 63 (providing that infringers can be fined up to four times their illegal income), *with* 2000 Patent Law, *supra* note 64, art. 58 (providing that infringers can only be fined up to three times their illegal income).

165. *Compare* 2008 Patent Law, *supra* note 161, art. 63 (“[I]f there are no illegal earnings, the fine will not be more than RMB 200,000 yuan.”), *with* 2000 Patent Law, *supra* note 57, art. 58 (“[W]here there is no illegal income, he may be imposed a fine of no more than 50,000 RMB.”).

The third amendment also gives the Patent Administrative Department more resources to investigate acts of passing off patents. Under the newly amended Chinese patent law, when infringement is suspected, the Patent Administrative Department may question the parties involved; investigate the facts; conduct an on-site inspection of the location where the act took place; review and copy contracts, invoices, accounting books, and other relevant documents; inspect the products; and seize or confiscate the products if there is proof that they are passed off products.¹⁶⁶

The third amendment also provides guidelines for determining the amount of compensation for the damages caused by infringers.¹⁶⁷ It mandates that the compensation be assessed based on the actual losses suffered by the patentee.¹⁶⁸ If the actual losses cannot be calculated, then the compensation must be assessed based on the profit made by the infringer through infringement.¹⁶⁹ When both of these figures cannot be determined, the damage can be assessed by referring to the appropriate multiple of the royalties for the patent.¹⁷⁰ If all three methods fail, the court can determine a compensation amount between CN¥10,000 (about US\$1500) to CN¥1,000,000 (about US\$150,000) based on the type of patent infringed and the facts

166. 2008 Patent Law, *supra* note 161, art. 64. (“The relevant patent administrative authority may, based on the evidence it obtains, query the related parties and conduct investigations concerning infringing activities when investigating the suspected passing-off matters; and may examine the place where the suspected infringement took place; view, reproduce any contracts, invoices, books and other materials related to the suspected infringement; examine the products related to suspected infringement, and may seal up or seize the products which have been proved to pass off patent rights.”).

167. *See id.* art. 65.

168. *See id.* (“The amount of compensation for the damage caused by patent infringement shall be assessed on the basis of the loss actually suffered by the patentee.”).

169. *See id.*

170. *See id.* (“If it is difficult to determine the losses which the patentee has suffered or the profits which the infringer has earned, the amount may be assessed by reference to the appropriate multiple of the amount of royalty fee for patent exploitation.”).

surrounding the infringement.¹⁷¹ The previous cap for judicially issued fines was CN¥500,000 (about US\$75,000).¹⁷²

Before the third amendment was enacted, the Chinese patent law did not clearly define what constituted designs and inventions.¹⁷³ Thus three paragraphs were added to Article 2 of the Chinese patent law to clarify the meanings of design, invention, and utility model. “Design” is defined as any “new design of a product’s shape, pattern or a combination thereof, as well as the combination of the color and the shape or pattern of a product, which creates an aesthetic feeling and is fit for industrial application.”¹⁷⁴ “Invention” means “any new technical solution relating to a product, a process or improvement thereof.”¹⁷⁵ “Utility model” covers “any new technical solution relating to a product’s shape, structure or a combination thereof, which is fit for practical use.”¹⁷⁶

The third amendment also heightened the standard for novelty. The Chinese patent law requires invention patents and utility model patents to possess novelty, creativity, and practical applicability.¹⁷⁷ Article 22 of the Chinese patent law was amended to adopt the “absolute novelty” standard that is internationally

171. *See id.* (“If it is difficult to determine the losses which the patentee has suffered, the profits which the infringer has earned, or the loyalty [sic] fee for patent exploitation, the people’s court may award damages no less than 10,000 yuan and no more than 1,000,000 yuan depending on the type of patent right, the nature and gravity of the infringing act etc.”).

172. Several Provisions of the Supreme People’s Court on Issues Concerning Applicable Laws to the Trial of Patent Controversies (promulgated by the Sup. People’s Ct. on June 19, 2001, effective July 1, 2001), *available at* http://www.sipo.gov.cn/sipo2008/zc/fq/flfg/zl/sfjs/200804/t20080415_377922.html.

173. *See* 2000 Patent Law, *supra* note 57, art. 2 (“In this law, ‘invention-creations’ mean inventions, utility models and designs.”)Feng, *supra* note 123, at 24 (declaring that utility models and designs had not been clarified before the third amendment to the Chinese patent law).

174. *See id.* art. 2. American case law has defined “design” in a similar way. *See In re Zahn*, 617 F.2d 261, 268 (C.C.P.A. 1980) (holding that a design patent protects the “design for an article, and is inclusive of ornamental designs of *all* kinds including surface ornamentation as well as configuration of goods.” (emphasis in original)).

175. 2008 Patent Law, *supra* note 161, art. 2.

176. *See id.*

177. *See id.* art. 22 (“Any invention or utility model for which a patent is to be granted shall be novel, inventive and practically applicable.”); *see also* John V. Grobowski & Yiqiang Li, *Amendments to the Patent Law of the People’s Republic of China*, FAEGRE & BENSON LLP, (Feb. 1, 2009), <http://www.facgre.com/showarticle.aspx?Show=9830>.

used.¹⁷⁸ The “absolute novelty” standard dictates that the invention not be known publicly either inside or outside China prior to the date of a patent application.¹⁷⁹ Prior to the third amendment, Chinese inventors were allowed to file for technology or invention patents that were known or used in other countries but not publicly known or used in China.¹⁸⁰ Under the 2008 Chinese patent law, Chinese patent applicants could not file for invention patents that were attributable to any existing technology published either inside or outside of China or technology that was used openly or known to the public in China.¹⁸¹ The third amendment also provides for a new kind of judicial order that could be used to preserve evidence in patent infringement cases by prohibiting an alleged infringer from destroying incriminating evidence when facing a suit. Patentees or plaintiffs can request the court to assist them in preserving evidence if the evidence is hard to obtain or has been destroyed.¹⁸²

The amended law also incorporated provisions designed to facilitate the process of getting a preliminary injunction. Article 66 provides that if the patentee can present evidence that (1) another person is infringing, or will soon infringe, his patent; (2) the infringer does not have any intention of stopping; and (3) such infringement would likely cause the patentee “irreparable

178. See 2008 Patent Law, *supra* note 161, art. 22 (“‘Novelty’ means that the invention or utility model shall neither belong to the prior art, nor has any entity or individual previously filed before the date of filing with the patent administration department under the State Council an application on an identical invention or utility model which was recorded in patent application documents or other gazetted patent documents published after the said date of filing.”).

179. *Id.* (“The ‘prior art’ referred to in this Law refers to any technology known to the public before the filing date of the patent application in China or abroad.”).

180. See Feng, *supra* note 123, at 53 (articulating that before the third amendment, the Chinese patent law allowed applicants to obtain patents for a technology or design “that is not used publicly or is not know by the public in other ways in China, but is actually used publicly or has corresponding designs abroad”); see also Yang & Yen, *supra* note 150, at 22 (claiming that the 2000 Chinese patent law “allows publicly known inventions that have not been specifically disclosed in publications in a foreign country to be patentable in China if it is not publicly known or used in China”).

181. See *supra* note 178 and accompanying text (describing what novelty is under the current Chinese patent law).

182. 2008 Patent Law, *supra* note 161, art. 67 (“In order to prevent infringing activity, under the circumstance that the evidence might be destroyed or later difficult to obtain, the patentee or a related injured party may before filing a law suit apply to the people’s court for evidence preservation.”).

harm,” the patentee can ask the court for a preliminary injunction.¹⁸³ The court then has forty-eight hours to make a decision.¹⁸⁴ If a concerned party is not satisfied with the ruling, he may apply for reconsideration, but only once.¹⁸⁵

The third amendment also allows for more non-infringement defenses by codifying the prior-art defense, which allows the accused to claim as a defense that the patented design or technology has been revealed in prior art or design.¹⁸⁶ This allows for quicker adjudication of cases by allowing defendants to prove their innocence without going through the formal adjudication process, which is split into two processes: the Patent Reexamination Board first must rule on the validity of the patent, and then a court will decide whether the patent is being infringed once it is found to be valid.¹⁸⁷ The case will stay in court until the Patent Reexamination Board determines the validity of the patent, causing lengthy adjudications of cases.¹⁸⁸

The third amendment lays out clearer terms prohibiting double patenting, which occurs when two or more inventions-creations are granted separate patents even though the main characteristic components protected by the patents are the same.¹⁸⁹ Double patenting occurs frequently in China because

183. See 2008 Patent Law, *supra* note 161, art. 66 (“Where any patentee or interested party has evidence to prove that another person is infringing or will soon infringe its or his patent right . . . it or he may, before filing a suit, apply to the people’s court for an order to stop the relevant acts.”).

184. See *id.*

185. See *id.*

186. See *id.* art. 62 (“During a patent infringement dispute, if the alleged infringer has evidence proving its or his technology or design belongs to the prior art or is a prior design, it will not constitute patent infringement.”).

187. See Yang & Yen, *supra* note 150, at 23 (explaining that the prior-art defense quickens the adjudication of infringement cases because a defendant’s innocence can be determined without going through the usual adjudication process).

188. See *id.* (claiming that patent litigation cases might not be resolved for years due to the adjudication process in China); see also USTR, *supra* note 93 (reporting that a patent infringement case takes four to seven years to complete in Chinese civil court).

189. See Bai et al., *What Does the Third Amendment to China’s Patent Law Mean to You?*, JONES DAY (Jan. 2009), <http://www.jonesday.com/newsknowledge/publicationdetail.aspx?publication=5806> (stating that double patenting occurs when applicants file for two patents for the same invention-creation); see also Feng, *supra* note 123, at 25–26 (“The so-called double patenting can be understood as the situation in which two or more . . . inventions-creations are applied for patent separately and are granted patents as their main technical characteristic components to be applied for protection are the same or identical technical solution.”).

applicants often file for both a utility model and invention patent for their invention-creation.¹⁹⁰ The third amendment added a provision to Article 9 that addressed this issue:

For any identical invention-creation, only one patent right shall be granted. However, with respect to the application of a utility model patent and invention patent for the identical invention-creation filed by the same applicant on the same day, the invention patent may be granted if this utility model patent right obtained first is still in force, and the applicant declares to abandon the obtained utility model patent has been granted.¹⁹¹

The third amendment thus allows an individual to apply for a utility or invention patent for the same invention-creation on the same day, but prohibits him from holding both a utility and invention patent for an invention-creation.¹⁹²

Prior to passing the third amendment, international enterprises that did not have a habitual residence or business office in China had to appoint a patent agency designated by the Patent Administration Department to act as their agent when applying for a patent or handling other patent-related matters.¹⁹³ With the changes brought by the third amendment, these international enterprises now need only appoint any “patent agency legally established to act on [their] behalf,”¹⁹⁴ and not necessarily one designated by the Patent Administration Department. This change makes it more convenient for international enterprises without habitual residences or business offices in China to choose patent agents to handle their patent-related matters.

190. See Bai et al., *supra* note 189 (“It has been a widespread practice [in China] of patent applicants to obtain invention patents and utility model patents on the same inventions.”); see also Yang & Yen, *supra* note 150, at 20 (“Double patenting presents a special problem under Chinese patent law because China offers both invention and utility model patents.”).

191. 2008 Patent Law, *supra* note 161, art. 9.

192. *Id.*; see Feng, *supra* note 123, at 27 (explaining that the 2008 patent law permitted the same applicant to apply for a utility model patent or an invention patent on the same day based on the same invention-creation without committing double patenting).

193. 2000 Patent Law, *supra* note 57, art. 10 (“Any assignment, by a Chinese entity or individual, of the right to apply for a patent, or of the patent right, to a foreigner must be approved by the competent department concerned of the State Council.”).

194. 2008 Patent Law, *supra* note 161, art. 19.

The amended Chinese patent law also provides that the Patent Administrative Department may grant a compulsory license to manufacture a medicine that has been patented in China and to ship the patented medication to other countries or regions, provided that the manufacturing process conforms to the provisions of the relevant international treaties to which China is a party.¹⁹⁵ In 2005, SIPO had already issued an order granting compulsory licenses for health purposes, but the amended Chinese patent law highlights and legitimizes this.¹⁹⁶ The third amendment also incorporates the “Bolar exemption,” which exempts someone from infringement if he is producing, utilizing, or importing patented medicine to provide the information as needed for administrative approval and for scientific research and experimentation.¹⁹⁷

The third amendment also addresses co-owner rights. Article 15 provides that if there is an agreement between co-owners regarding the exploitation of a jointly owned patent, the agreement must be followed.¹⁹⁸ If there is no such agreement, the co-owner may exploit the patent without another owner’s consent by licensing it non-exclusively, but all royalties from that licensing must be distributed between the co-owners.¹⁹⁹ In

195. *See id.* art. 50 (“For the purpose of public health, the patent administrative department of the State Council may grant a compulsory license to manufacture a drug which has been granted a patent right in China and to export it to the countries or regions specified in related international conventions in which China is a contracting member.”).

196. *See* Approach to Implementing Compulsory License Involving Issues Relating to Public Health (promulgated by the State Intellectual Property Office of P.R.C. on Nov. 29, 2005, effective Jan. 1, 2006), *available at* http://big5.sipo.gov.cn/www/sipo2008/zwgs/ling/200804/t20080402_366969.html (explaining that as long it is in compliance with the TRIPS agreement, SIPO has the authority to grant compulsory licenses so that patented drugs can be delivered to regions and countries that need them); *see also* Yang & Yen, *supra* note 150, at 24 (stating that Article 50 was mostly an attempt to clarify the patent law since SIPO had already authorized the granting of compulsory licenses for health purposes in 2005).

197. *See* 2008 Patent Law, *supra* note 161, art. 69, § 5 (providing that infringement does not include the “providing of information needed for the administrative approval, manufacture, use, import of a drug or a medical apparatus, and exclusively for such manufacture any import of a patented drug or a patented medical apparatus”).

198. *See id.* art. 15 (“If the co-owners of a patent application right or patent right have an agreement on the exercise of those rights, the agreement shall apply.”).

199. *See id.* (“If there is no such agreement, any co-owners may independently exploit or license others to exploit the patent through ordinary licenses. Any royalties obtained through licensing others to exploit the patent shall be distributed amongst all the co-owners.”).

addition, exploiting the patent in other ways, such as granting an exclusive license, requires the consent of all the co-owners.²⁰⁰ Article 8 reaffirms Article 15's rules on co-owner rights.²⁰¹

The third amendment made significant changes to the Chinese patent law in the areas of patent protection and patentable subject matter definition. It also provided clear terms about compulsory licensing and co-owner rights and added the Bolar exemption as well as provisions about double patenting. The actual effects of these changes, however, are yet to be determined.

C. *Will the Third Amendment Bring Great Benefits to International Litigants or Maintain the Status Quo?*

Some argue that the third amendment has revolutionized the way multinational companies will compete in the Chinese market.²⁰² At least one optimistic commentator, Benjamin Bai, thinks that the amended Chinese patent law has a great deal to offer, and if international companies become better acquainted with China's IP protection system, they can use the existing protections to their own advantage.²⁰³ Bai acknowledges that international companies are reluctant to file patent infringement cases in China because of the misconception that the Chinese

200. *See id.* ("Except for the situation provided in the above paragraph, the exercise of a jointly-owned patent application right or patent right shall be consented by all co-owners.").

201. *See id.* art. 8. ("For an invention-creation made by two or more entities or individuals, or made by an entity or individual in execution of a commission given to it or him by another entity or individual, the right to apply for a patent belongs, unless otherwise agreed upon, to the entity or individual that made, or to the entities or individuals that jointly made, the invention-creation. After the application is approved, the entity or individual that applies for it shall be the patentee.").

202. Bai et al., *supra* note 189 ("The Third Amendment to the Patent Law contains sea [sic] changes that will significantly affect how Chinese and multinational companies will compete on the basis of patents in this emerging market."); Phong Nguyen, *Changing Landscape: Introduction to the Third Amendment to the Chinese Patent Law*, ABA (2009), <http://www.abanet.org/buslaw/committees/CL983500pub/newsletter/200906/nguyen.pdf> ("The third amendment will change the way foreign companies obtain patent protection and conduct business in China.").

203. Benjamin Bai, *Yes, China Does Protect Intellectual Property*, WALL ST. J., Feb. 11, 2010, <http://online.wsj.com/article/SB10001424052748704259304575044150656353806.html> ("The key is for foreign businesses to understand how IP protection works in China and to take better advantage of the protections that exist.").

court system favors domestic plaintiffs.²⁰⁴ He attempts to debunk this belief, however, by pointing to *Neoplan v. Beijing Zhongtong Xinghua Automobile Selling Co.*, a Chinese case in which a German bus company won a US\$3,000,000 judgment against two Chinese companies for patent infringement.²⁰⁵ He also points to the State Council's Outline of the National Intellectual Property Strategy as a clear indication of China's policy makers' desire to build a functional IP regime.²⁰⁶

Proponents argue that the absolute novelty requirement stipulated by the third amendment should also appease international companies' fear and skepticism of the court system and should also encourage more international investment in China.²⁰⁷ Under the absolute novelty requirement, Chinese companies cannot file for a drug patent if the drug has been patented elsewhere in the world.²⁰⁸ The third amendment also brings Chinese patent law closer in line with international standards, which should encourage multinational companies to look at the patent protection system in China with a new and more optimistic eye.²⁰⁹

Even though the third amendment is seen as a symbol of the Chinese central government's commitment to develop and

204. *Id.* (arguing that international companies' fear that they are prejudiced by the Chinese court system is unfounded).

205. Bai, *supra* note 203 (citing the *Neoplan* case as evidence that international companies are not prejudiced in China); see *Neoplan v. Beijing Zhongtong Xinghua Auto. Selling Co.*, (Beijing Interm. People's Ct. Jan. 14, 2009).

206. Bai, *supra* note 203 ("[The] 'Outline of the National Intellectual Property Strategy' . . . acknowledges that robust IP protection is a critical component of an innovation-driven economy.").

207. See Nguyen, *supra* note 202 (arguing that the absolute novelty requirement eliminates a loophole often exploited by Chinese companies); see also Hepeng Jia, *China Tightens IP Protection, but Concerns Linger*, 27 *NATURE BIOTECH.* 787, 787 (2009) (listing the absolute novelty requirement as one of the several improvements in the Chinese patent law).

208. See 2008 Patent Law, *supra* note 161, art. 2 (explaining that a patent will only be granted if the invention/technology is not publicly known or used in China and abroad); see also Jia, *supra* note 207 ("With the new 'absolute' principle, a Chinese patent can only be issued if the invention is totally new worldwide.").

209. See Bai, *supra* note 203 (asserting that the amended patent law is more in line with the international standards, which should encourage international companies to assume that China forcefully protects patents); Grobowski & Li, *supra* note 177 (indicating that the third amendment was designed partly to align Chinese patent law with international standards).

implement more effective patent laws,²¹⁰ some scholars note that the Chinese central government's dedication to implementing efficient patent protection laws is not mirrored on the local level.²¹¹ These scholars believe that without the participation of the local governments and stricter enforcement of the law, pharmaceutical counterfeiting will continue to be a problem.²¹²

The central government consists primarily of legislative and policy-making bodies, and cooperation is therefore needed at the local level to implement and enforce laws.²¹³ In recent years, there has been an increase in the independence and autonomy of Chinese local governments, which has enhanced the stability of the counterfeit drug market.²¹⁴ Local officials are known to accept bribes to ignore the counterfeiting problems and may even participate in the counterfeiting business themselves.²¹⁵ Counterfeiters also provide indirect financial benefits to

210. See *supra* note 209 and accompanying text (discussing that the third amendment brought the Chinese patent law more in line with international standards).

211. See *infra* notes 216–17 and accompanying text (explaining that local governments often protect the counterfeiters because the counterfeiters are vital to their respective economies).

212. See Bronshtcin, *supra* note 2, at 440 (arguing that the Chinese central government's fight against counterfeiting could work if the local government corruption that undermines existing counterfeit drug regulations is eliminated); *c.f.* Nelson et al., *supra* note 9, at 1089 (noting that enforcement efforts are hampered by local corruption and protectionism).

213. See Bronshtein, *supra* note 2, at 459 (“[T]his central level authority is comprised mainly of legislative and policy-making bodies, while actual implementation and enforcement of law occurs at the local level.”); Chow, *supra* note 88 (arguing that although the central government understands the importance of protecting IP, it is just comprised of legislative and policy-making bodies; actual implementation and enforcement of IPR laws has fallen on local governments, which are slow to embrace this commitment).

214. See Bronshtcin, *supra* note 2, at 459 (arguing that “there has been an increased trend toward solidifying local autonomy in China” and these increasingly powerful local governments support the counterfeiting business); Evans, *supra* note 63, at 590 (arguing that China was faced with the rise of corruption and regionalism due to decentralization); Nelson et al., *supra* note 9, at 1089 (“Enforcement efforts, particularly at the local level, are hampered by poor coordination among Chinese Government ministries and agencies [and] local protectionism and corruption.”).

215. See Evans, *supra* note 63, at 591 (“Moreover, many local officials directly profited from piracy through kickbacks and bribes, while other high-ranking officers were involved firsthand in the production of illegal goods and services.”); see also Wong, *supra* note 41, at 965 (“[L]ocal officials often profit from counterfeit goods through kickbacks or bribes or may even be involved with the production of illegal goods and services.”).

communities by patronizing their restaurants and hotels.²¹⁶ In certain localities, the drug counterfeiting business has become so integrated in the local market that it is hard to differentiate legitimate businesses from illegal ones.²¹⁷ In other instances, officials are aware of counterfeit pharmaceuticals and related activities, but chose not to report them for fear that it would taint China's reputation.²¹⁸ When officials do not report such activity, however, they often become scapegoats and receive severe punishments when the counterfeit pharmaceuticals scandals are made public.²¹⁹ Scholars question if the goal of keeping Chinese citizens safe from counterfeit drugs is seen as less valuable than the potential earning power of those drugs.²²⁰

216. Bronshtcin, *supra* note 2, at 460 (“[L]ocal 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.”); Chow, *supra* note 88 (mentioning that in some localities, “legitimate businesses such as hotels, restaurants, nightclubs, storage and transportation companies have been created to support the trade in counterfeit goods”).

217. Chow, *supra* note 88 (explaining that tax payments and the creation of lawful businesses have incorporated counterfeiting into the legitimate local job market, and that the removal of counterfeiting in certain localities would devastate the local economy); *see also* Bronshtcin, *supra* note 2, at 460 (“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 business.”).

218. *See* William O. Hennessey, *Protection of Intellectual Property in China (30 Years and More): A Personal Reflection*, 46 HOUS. L. REV. 1257, 1289 (2008) (declaring that some officials knew that milk products were laced with melamine, but failed to report it because they feared getting in trouble for tainting China's name during the 2008 Olympics). *See generally* Jim Yardely & David Barboza, *Despite Warnings, China's Regulators Failed to Stop Tainted Milk*, N.Y. TIMES, Sept. 27, 2008, at A1 (discussing how the Chinese government tried to silence the concerns about the tainted milk during the Olympics to put up a good front, despite receiving many warnings and concerns).

219. *See, e.g.*, Hennessey, *supra* note 218, at 1289 (reporting that, when the scandal was publicized, the same officials who failed to report the melamine laced milk out of fear that they would be punished for making China look bad during the 2008 Olympics were punished for not reporting it earlier); *More Officials Punished over Sanlu Scandal*, CHINA.ORG.CN (Mar. 20, 2009), http://www.china.org.cn/government/central_government/2009-03/20/content_17477922.htm (announcing that the responsible health officials were either demoted or fired for their failure to report the melamine-laced milk).

220. *See, e.g.*, Hennessey, *supra* note 218, at 1290 (questioning “if the right of the public to be free from dangerous products (including counterfeit medicines) is ‘balanced’ against a local ‘quick buck’”); *see also* Gregory H. Fuller, Comment, *Economic Warlords: How De Facto Federalism Inhibits China's Compliance with International Trade Law and Jeopardizes Global Environmental Initiatives*, 75 TENN. L. REV. 545, 556–69 (2008) (discussing the conflict between drug regulation and IP protection in China).

Scholars are equally skeptical of the Chinese court system, which is reliant on the local government in many areas.²²¹ Judges risk the loss of benefits or even removal if they rule in a way that the local government dislikes.²²² Judges are also often improperly trained and have little knowledge about patent infringement, which prolongs the adjudication of these cases.²²³ The USTR recognized that there has been an increase in judicial enforcement related to infringing activities in Beijing and Shanghai, but this increase is limited to those areas.²²⁴

Other scholars criticize the compulsory licensing provisions in the newly amended Chinese patent law, arguing that it destroys the purposes of patents and discourages international companies from obtaining pharmaceutical patents in China.²²⁵ Scholars argue that the language of these provisions is unclear and affords courts too much discretion in determining whether a compulsory license should be granted.²²⁶ Some even predict that officials will use the vague wording of the provisions and the

221. See, e.g., Bronshtein, *supra* note 2, at 461 (“In fact, many leaders of Chinese local governments view courts simply as ‘subordinate departments of the local government.’”); Wong, *supra* note 41, at 970 (“Fear of removal can result in judges unreasonably denying motions for transfer of forum, delivering verdicts favorable to local parties or refusing to respect the former judgments by other courts.”).

222. See sources cited *supra* note 221 (discussing the challenges that judges face when they do not rule to the liking of the local government).

223. See USTR, *supra* note 93 (explaining that because most judges lack necessary technical training, the adjudication process is inefficient, unpredictable, and unnecessarily long); see also Bronshtein, *supra* note 2, at 461 (emphasizing that there is a shortage of adequately trained judges).

224. See USTR, 2010 SPECIAL 301 REPORT 20 (2010), available at http://www.ustr.gov/webfm_send/1906 (“There have been some improvements, including judicial enforcement related to infringing activities in retail markets in Beijing and Shanghai. Other welcoming steps include judicial authorities sentencing wholesalers to prison terms, and holding retail market landlords liable for failing to take appropriate measures to prevent infringement. Unfortunately, outside Beijing and Shanghai, there have been limited efforts to hold landlords liable for infringement that occurs on their premises.”).

225. Ronald A. Cass, *Patent Reform with Chinese Characteristics*, WALL ST. J., Feb. 10, 2009, <http://online.wsj.com/article/SB123419814824764201.html> (“Compulsory licensing threatens the fundamental property right that patents confer.”); see also Yang & Yen, *supra* note 150, at 123 (stating that the compulsory licensing provisions might discourage pharmaceutical companies from obtaining additional patents in China).

226. See Cass, *supra* note 225 (arguing that the compulsory licensing provisions contain many vague terms that allow a wide range of discretion); see, e.g., 2008 Patent Law, *supra* note 161, art. 55 (“In the decision granting the compulsory license for exploitation, the scope and duration of the exploitation shall be specified on the basis of the reasons justifying the grant.”).

“discretionary powers” given to them to protect Chinese firms and to hinder the most powerful international competitors.²²⁷

Some scholars, however, argue that China could use the amended Chinese patent law to generate goodwill among developing and undeveloped countries that do not have the ability to manufacture the drugs themselves by utilizing compulsory licenses to provide exportation of pharmaceuticals to these countries.²²⁸ Scholars are also wary of the addition of the Bolar exception because it allows for the manufacturing of patented drugs without obtaining licenses and warn pharmaceutical patent holders against this newly adopted exception to patent infringement.²²⁹

Even though the third amendment significantly increases the fines for patent infringement and provides for more judicial and administrative tools to fight patent infringement, patent infringement will continue to occur if the Chinese patent law is not enforced. The third amendment introduces some provisions that can be easily manipulated into a defense against patent infringement, such as the Bolar exemption and compulsory licensing. Local governmental protectionism and corruption pose as major barriers to the proper enforcement of the Chinese patent law.

Before the third amendment was enacted, the Chinese patent law did not sufficiently deter patent infringement. The third amendment drastically improves the patent protection in China. Advocates of the third amendment believe that it cultivates more trust in the Chinese patent protection system. Skeptics argue that lack of enforcement of the patent law at the

227. See, e.g., Cass, *supra* note 225 (“If history provides guidance, officials will be tempted to use discretionary powers to protect Chinese firms and to handicap the strongest foreign competitors.”); USTR, *supra* note 5, at 14–15 (stating that there still exists longstanding concerns that domestic companies are favored over multinational companies in China, especially given that the Chinese government is considering policy changes in the area of compulsory licensing of patented inventions, which can be used against international companies).

228. See, e.g., Yang & Yen, *supra* note 150, at 24 (“China could use Article 50 to generate significant goodwill among developing and undeveloped countries.”).

229. See George Chan, *Amendments to China’s Patent Law*, IP AUSTRALIA (2009), http://www.ipaustralia.gov.au/pdfs/general/patent_law_updates_China.pdf (warning patentees in the pharmaceutical and biotechnological industry that the Bolar exemption is an exemption from patent infringement); Jia, *supra* note 207, at 788 (stating that the new rules allows generic producers to study the original patented products claiming that it is research without being charged with infringement).

local level will perpetuate counterfeiting regardless of the changes made by the third amendment.

III. *THE CHINESE PATENT LAW WILL CONTINUE TO BE
INEFFECTIVE AS LONG AS LOCAL GOVERNMENT
CORRUPTION AND PROTECTIONISM EXISTS*

Scholars have predicted both positive and negative effects of the third amendment to the Chinese patent law. While the third amendment was enacted with the purpose of improving patent protection in China and making the Chinese patent law more comprehensive, it will have very little effect if the Chinese patent law is not stringently enforced. Without first dissolving local government autonomy and dissipating local governmental protectionism and corruption, the proper enforcement of Chinese patent is highly improbable. This Part first acknowledges the major advances that the third amendment has brought to patent protection in China, but it also recognizes that these advantages cannot be realized if the Chinese patent law is not properly enforced. It then discusses the obstacles to the enforcement of the Chinese patent law and suggests how to eliminate these obstacles.

The third amendment has made significant changes to the Chinese patent law and perhaps eases the minds of international investors looking to introduce a new drug into the Chinese market.²³⁰ Certain provisions of the amendment reflect the Chinese government's dedication to improving patent protection in China,²³¹ but some scholars question whether some of the provisions will be abused.²³² The amended Chinese patent law is, however, more in line with international standards.²³³

Despite the improvements that the third amendment brought to Chinese patent law, the law could still benefit from additional changes. Instead of giving courts the option of

230. *See supra* Part II (addressing the provisions of the newly amended Chinese patent law that tighten patent protection).

231. *See supra* notes 163–82 and accompanying text (discussing the provisions that increase the fines for patent infringement, help preserve evidence, and redefine novelty).

232. *See supra* notes 225–27 and accompanying text (discussing the potential problems of the compulsory licensing provisions).

233. *See supra* note 209 and accompanying text (stating that the third amendment made the Chinese patent law more in line with the international standard).

holding certain infringers criminally liable,²³⁴ the Chinese patent law should mandate that drug counterfeiters be held criminally liable in all cases to deter future counterfeiting. Pharmaceutical counterfeiting is a serious offense that can affect the global economy and health.²³⁵ Even though the amended Chinese patent law increases the fines for infringement, it is unclear whether infringers would be given a portion of that money. If not, additional funding should be provided for administrative proceedings. A large portion of the confiscated profits of the guilty infringers should be used to compensate the infringees.²³⁶

The lack of a discovery process has also significantly hindered US litigants, who are accustomed to having such a process, from successfully winning a patent litigation suit in China.²³⁷ Mandating a discovery process may uncover evidence that may otherwise be undiscovered. In addition, ensuring that judges are given as much relevant evidence as possible may encourage better-informed decisions.

Improving patent protection rights is the first step to developing an efficient patent protection system, but proper enforcement of those rights is equally important. China needs to address how to effectively enforce the Chinese patent law. The existence of local governmental corruption and protectionism is a major hindrance in the enforcement of patent protection laws.²³⁸ As long as local government officials refuse to ensure effective adjudication of patent infringement cases and proper enforcement of patent protection rights, pharmaceutical counterfeiting will continue to be a problem.²³⁹

To resolve this lack of enforcement at the local levels, the central government can work toward changing the funding

234. *See supra* notes 60, 92 (citing Articles 58 and 64 of the Chinese patent law prior to 2009, which state that if the circumstances are serious enough, the infringer should be prosecuted for criminal liability).

235. *See supra* note 10 and accompanying text (discussing the economic and health risks of counterfeit drugs).

236. *See supra* note 61 and accompanying text (discussing the disadvantages of an administrative system that offers minimal monetary compensation for infringees).

237. *See supra* note 72 and accompanying text (discussing how plaintiffs in China must collect their evidence).

238. *See supra* notes 215–19 and accompanying text (discussing how local governmental protectionism and governmental corruption perpetuates pharmaceutical counterfeiting).

239. *See supra* notes 215–19 and accompanying text.

system of administrative agencies. Instead of having local governments provide the necessary funds for administrative agencies, the central government can provide that funding, which would dissipate the influence of local governments over administrative agencies.²⁴⁰ The central government can also develop a training program for SIPO agents to ensure that there is uniformity among the SIPO offices in determining if patents are invalid or are being infringed.

To ensure unbiased adjudication of patent infringement cases, the central government can also provide adequate training for judges. The Supreme People's Court has wisely reserved about fifty courts to be first-instance courts for adjudication of patent infringement cases,²⁴¹ reasoning that patent infringement cases tend to be more complex. The judges of those courts, however, are often not properly trained, causing the adjudication of patent infringement cases to be slow and inefficient.²⁴²

With the counterfeit business so deeply integrated into the local economies of certain regions, a crackdown on these businesses may lead to the economic demise of these regions.²⁴³ To prevent this, these regions' economies must be slowly weaned off the counterfeiting business. More funding should be provided for pharmaceutical and biotechnological research and development. Providing Chinese companies with the funding to develop their own drugs may redirect their energies from counterfeiting to developing their own patentable drugs. The central government should develop a task force whose sole duty is to investigate and stop counterfeiting businesses. Simultaneously encouraging companies to engage in legitimate business practices and to halt counterfeiting actions will help facilitate the gradual movement of local economies' dependency on counterfeiting businesses to legitimate businesses.

240. *See supra* notes 63, 214–29 and accompanying text (discussing how the local governments are hesitant to provide proper funding for administrative agencies because the drug counterfeiting business accounts for a large portion of the local economy).

241. *See supra* note 67 and accompanying text (stating that about fifty Intermediate People's Courts were appointed to be first instance courts for patent infringement cases).

242. *See supra* note 223 and accompanying text (commenting on how judges' lack of expertise negatively impacts the adjudicative process of patent infringement cases).

243. *See supra* note 217 and accompanying text (stating that the shutdown of the counterfeiting business in certain places would seriously harm local economies).

Other countries' distrust of China's patent system is another hurdle that China needs to overcome.²⁴⁴ China needs to build up other countries' trust in her patent system by demonstrating that she is serious about protecting patents. Fortunately for China, her rich resources and large population have lured many international companies to invest in her economy, making her the third-largest trading nation and the fourth-largest economy in the world.²⁴⁵ Many multinational companies, however, warily enter the Chinese economy.²⁴⁶ If China wishes to legitimize herself as a major player in the global economy, she should invest more time and energy in improving and enforcing her IP laws.²⁴⁷

There are mixed feelings surrounding the third amendment to the Chinese patent law. Some scholars think it is a major leap forward,²⁴⁸ while others are still proceeding with caution.²⁴⁹ China cannot win other nations' trust instantly, but she can take further steps to show her dedication to improving her patent protection system, such as encouraging her domestic companies to develop their own products, which she has already begun doing by implementing the absolute novelty requirement into her patent law.

Until China is recognized as having an effective patent law system, multinational corporations should consider getting their patent infringement cases adjudicated, even though it may take longer than the administrative route.²⁵⁰ While judges are not completely free from influence by the local government,²⁵¹

244. See, e.g., *supra* note 5 and accompanying text (stating that the United States claims that China has one of the least effective IP regimes in the world).

245. See *supra* note 47 and accompanying text (citing China's standing in the global economy).

246. See, e.g., *supra* note 145 and accompanying text (stating that GlaxoSmithKline probably abandoned its Avandia patent because it was contemptuous of the Chinese patent law).

247. See *supra* notes 2–5 and accompanying text (discussing China's desire to become an integral player in the global economy and attempts to improve her IP system to accomplish this goal).

248. See *supra* notes 204–10 and accompanying text (presenting the scholarly arguments in favor of the third amendment to the Chinese patent law).

249. See *supra* notes 204–42 and accompanying text (presenting the different outlooks on the third amendment to the Chinese patent law).

250. See *supra* note 131 and accompanying text (stating that international litigants might have to wait several years before their patent infringement cases are adjudicated).

251. See *supra* note 222 and accompanying text (discussing the challenges judges might face when they do not rule to the favor of the local governments).

litigants might consider the option of having their case adjudicated in a region that is stricter about enforcing the Chinese patent law.²⁵²

CONCLUSION

The Chinese patent law has changed dramatically since its enactment in 1984. As more and more multinational companies invest in the Chinese market, China is increasingly feeling the pressure to improve her IP system.²⁵³ These corporations, however, are cautious to participate in the Chinese economy because of the prevalence of counterfeiting in China.²⁵⁴ Perhaps the most dangerous of all the counterfeiting businesses is pharmaceutical counterfeiting.²⁵⁵

For many years, it seemed that the Chinese patent law was ineffective in stopping pharmaceutical counterfeiting, but the third amendment brought a promising glow as China tightens patent protection laws and increases the penalty of patent infringement.²⁵⁶ The effectiveness of the newly amended Chinese patent law, however, is not just contingent upon the substance of the law, but will largely depend on how effectively it is enforced. Local protectionism and corruption pose major barriers to the effective enforcement of these laws.²⁵⁷ If China can effectively dilute the hold that local governments have over regional administrative offices, then these barriers would be largely eliminated. The Chinese central government can start by providing more funding for pharmaceutical and biotechnological research and development. The central

252. See, e.g., *supra* note 224 and accompanying text (commenting on how courts in Beijing and Shanghai have been enforcing IP protection rights more strictly in recent years).

253. See *supra* note 3 and accompanying text (stating that China is trying to improve her domestic IP laws in her crusade to become a major player in the global economy).

254. See *supra* note 6 and accompanying text (stating that over 4000 new patent infringement cases were filed in China annually in 2007 and 2008).

255. See *supra* note 10 and accompanying text (discussing the harmful effects of counterfeit drugs).

256. See *supra* note 159 and accompanying text (stating that the third amendment to the Chinese patent law will improve the protection of IP rights by increasing monetary penalties).

257. See *supra* note 215 and accompanying text (stating that local officials benefit from and support the counterfeiting businesses).

government should also look into providing funding for administrative agencies and properly training the judges who handle patent infringement cases. Until the local governments' influence over administrative agencies and courts is dissipated, it is hard to speculate about how effectively the newly amended Chinese patent law will be implemented and enforced and, in turn, how the third amendment will affect pharmaceutical counterfeiting in China. The local governments' control on local agencies and courts will take some time to loosen; in the meantime, other measures such as the development of task forces to investigate and stop pharmaceutical counterfeiting and implementation of stricter criminal penalties against counterfeiters should be taken. Victims of infringement can also help themselves by choosing a jurisdiction that is more diligent in pursuing counterfeiting.