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# Pfizer's Viagra Patent and the Promise of Patent Protection in China

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## I. INTRODUCTION

On July 7, 2004, Pfizer Inc. announced that the Chinese State Intellectual Property Organization (SIPO) Patent Reexamination Board had overturned Pfizer's patent for sildenafil citrate, the main ingredient in the popular erectile dysfunction drug Viagra.<sup>1</sup> The response from Pfizer and from other international or multinational pharmaceutical companies was immediate.<sup>2</sup> Legal and business commentators postulated that China was demonstrating its inability to conduct itself in accordance with the guidelines set by its membership in the World Trade Organization (WTO) and was regressing back to its old ways of state-tolerated violations of intellectual property rights.<sup>3</sup> Approximately one

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1. Associated Press, *Chinese Dismiss Patent for Viagra*, SAN JOSE MERCURY NEWS, July 7, 2004, available at 2004 WLNR 2937426.

2. Associated Press, *Pfizer Patent for Viagra Overturned in China*, CHI. SUN TIMES, July 8, 2004, available at 2004 WLNR 11709102 (quoting Pfizer Inc.'s statement that "[the company] is extremely disheartened by this recent action" and noting that foreign drug companies had been watching the Pfizer case as a test of China's commitment to intellectual property rights); Jake Lloyd-Smith, *U.S. Drug Giant Lashes Out at China Patent Decision, May Curb Investment*, CAN. PRESS, July 16, 2004, available at 2004 WLNR 85647918 ("Pfizer Inc. . . . lashed out Friday at Chinese regulators' recent decision to overturn its local patent for Viagra, warning that it might cut future investment in the world's most populous country.").

3. See, e.g., *China's Viagra Heist*, ASIAN WALL ST. J., July 9, 2004, at A7 ("[T]his week China decided to ignore market principles, its own World Trade Organization commitments and the long-term interests of its people by overturning [Pfizer's sildenafil citrate] patent"); James B. Altman, Greg Mastel, & Daniel P. Wendt, *Smart Pills: Protecting IP Rights Overseas*, IP LAW & BUSINESS, Sept. 2004, at 22; Phelim Kyne, *Pfizer*

month after the China SIPO announcement regarding the Pfizer patent, U.K. pharmaceuticals company GlaxoSmithKline PLC abandoned its formulation patent for rosiglitazone, the major component of its diabetes drug Avandia, in the face of a patent challenge by three Chinese drug makers.<sup>4</sup> Glaxo cited the China SIPO decision regarding the Viagra patent as indicating that Glaxo would be unable to obtain meaningful protection of this important drug.<sup>5</sup>

Fallout from the Pfizer patent case continues, and the long-term significance of the China SIPO decision remains uncertain.<sup>6</sup> However, despite the complaints of Pfizer and the pharmaceutical industry, the Pfizer case clearly indicates the continuing development and progress of the Chinese patent law system. As noted recently by Professor Peter Yu, the action taken by the Chinese pharmaceutical industry to legally challenge the Pfizer patent demonstrates significant progress by China toward rule of law in the intellectual property rights arena.<sup>7</sup> Prior to the Pfizer case, the common approach of the Chinese pharmaceutical industry to getting around drug patents was simply violating them and creating infringing drugs to flood the Chinese market.<sup>8</sup> The approach of the Chinese companies in the Pfizer case suggests that the Chinese are beginning to appreciate the value of patent laws.<sup>9</sup> However, the case also exposes substantial limitations in the Chinese patent law—although it seems that these limitations are not necessarily of the character most often cited by foreign

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*in China Faces The Threat of Losing Its Patent on Viagra*, ASIAN WALL ST. J., Nov. 29, 2002, at A4 (“Patent experts warn an adverse ruling poses a potential threat to the patents of other foreign drug companies and will raise doubts about China’s commitment to international patent and intellectual property rights standards.”).

4. Phelim Kyne & Leslie Chang, *Glaxo Gives Up Patent, Avoiding Fight in China*, ASIAN WALL ST. J., Aug. 19, 2004, at A1.

5. *Id.*

6. Pfizer filed an appeal of the decision of the China SIPO on September 28, 2004, in the Beijing First Intermediate People’s Court. Nicole Ostrow, *Pfizer Appeals China’s Revocation of Viagra Patent*, Sept. 28, 2004, (*Update 3*), <http://quote.bloomberg.com/apps/news?pid=10000080&sid=a71iUyLFelwU&refer=asianews?pid=10000103&sid=az8zaBVnPJOE&refer=us>.

7. Peter K. Yu, *Viagra’s Upside: Rejecting Pfizer’s Patent was a Sign of Progress in China*, IP LAW & BUSINESS US, Oct. 2004, at 49.

8. *See id.*; Yahong Li, *The Wolf Has Come: Are China’s Intellectual Property Industries Prepared for the WTO?*, 20 UCLA PAC. BASIN L.J. 77, 93-94 (2002).

9. Yu, *supra* note 7, at 49.

pharmaceutical companies and U.S. trade representatives.<sup>10</sup>

International drug and chemical companies eye the Chinese market because of its size, but remain wary of the legal system and criticize the weak protections afforded to pharmaceuticals by the Chinese patent law system. For example, Rohm & Haas Co., E.I. du Pont de Nemours & Co., and Eli Lilly & Co. all operate within China's borders, but have not been willing to establish comprehensive research and development facilities in China.<sup>11</sup> Concerns about intellectual property protection also have kept these companies from importing the most current technology into the Chinese market.<sup>12</sup> Nevertheless, increased competition in China has resulted in a push to place some of the most current pharmaceuticals in the Chinese market.<sup>13</sup>

From one perspective, it seems odd that the patent laws that currently exist in China do not adequately protect intellectual property rights (IPRs): Chinese patent law is similar to the patent laws of other WTO nations, having borrowed significantly from both United States and European Union laws.<sup>14</sup> If the laws similar to China's IPR laws are adequate to protect IPRs in the U.S. and the EU, it seems these laws should *per se* be adequate to protect IPRs in China. The failure of the laws to do so indicates China's lack of commitment to IPR protection. Alternatively, it can be argued that the recent cases of Chinese pharmaceutical companies using China's patent laws to challenge foreign-held patents indicates a new level of acceptance of China's IPR laws among

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10. The U.S. government and business sector often characterize the limitations of the Chinese patent law as the result of either an inept enforcement system or a failure of the rule of law. *See, e.g.*, Chris Buckley, *China is Told Again to Open Markets*, N.Y. TIMES, Oct. 29, 2003, at W1 (quoting US Commerce Secretary Donald Evans, "When it comes to intellectual property right protection [in China,] all observers would say they are not there"); Sabra Chartrand, *Stepping Up The Pressure Against Piracy in China*, N.Y. TIMES, Dec. 6, 2004 at C7; American Chamber Of Commerce - China, *2004 White Paper Intellectual Property Rights*, (2004), <http://newfirstsearch.oclc.org>; Jeffrey Silva, *Chamber of Commerce Points out Problems with Chinese Wireless Pledge*, RCR WIRELESS NEWS, Sept. 16, 2002, at 17.

11. Shu Shin Luh, *Let 100 Capitalists Bloom: China Pries Open Some of its Rules and Regulations Ahead of the WTO Timetable*, CORP. COUNS. (MAG.), Oct. 2003, at 132.

12. *Id.*

13. *Id.* (quoting Cherry Fan, in-house China counsel for Rohm & Haas in Shanghai, "Now competition [with other companies] is fierce. So how are we going to bring technology that is new and targeted toward the Chinese consumers, but at the same time protect ourselves against infringement?").

14. *See infra* notes 22-26 and accompanying text.

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domestic businesses. From this perspective, the ability of China's domestic businesses to realize direct benefits from China's patent laws is necessary to the integration of intellectual property laws in China's legal system.<sup>15</sup>

This article presents an argument for the latter perspective of patent laws in China, asserting that while the concerns of foreign pharmaceutical corporations regarding the protection of IPRs in China are quite real and substantial, the recent cases involving Pfizer and GlaxoSmithKine demonstrate the growing acceptance and success of patent protection in China. Following this perspective, concern over the domestic pharmaceutical industry's use of the patent challenge procedure as a competitive tool, as in the case of Viagra, is misplaced, as this type of business strategy is commonplace in the U.S. and EU. Rather, attention should be directed to refining China's patent laws so that disclosures made to the China SIPO by foreign corporations cannot be used to circumvent the patent process.

Part II of this paper includes a brief introduction to China's patent law with a particular focus on the process of patent invalidation that is currently affecting Pfizer in its attempt to enforce patent rights in Viagra. The concept of intellectual property rights did not develop organically in China, but rather was introduced largely as a result of Western trade demands in the twentieth century. Only by realizing a direct benefit from IPR enforcement will the Chinese respect the laws enforcing IPRs. It is precisely from such recognition of direct benefits from the enforcement of IPRs that the concept of legal patents arose in the West.

Part III of this paper presents the recent situation involving the Chinese patent held by Pfizer and discusses how it demonstrates an increased appreciation for patent law among domestic businesses in China. Further, according to a proper application of Chinese law, the outcome of the challenges to these foreign-owned patents should be expected from the Chinese patent system, and is not out-of-step with the decisions of other countries regarding Pfizer's Viagra patent. As the domestic pharmaceutical industry continues to grow in China, businesses

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15. See, e.g., Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U.L. REV. 131, 207 (2000).

will be increasingly incentivized to utilize the existing patent laws both to protect their own inventions and as a strategic tool to compete against foreign corporations.

## II. A BRIEF INTRODUCTION TO CHINESE PATENT LAW

China is the oldest continuous civilization on Earth, dating back nearly 5,000 years. However, despite the clear creativity and inventiveness of the Chinese people,<sup>16</sup> the Chinese culture never internally developed a concept of intellectual property rights.<sup>17</sup> The reasons for this lack of an intellectual property concept seem to be best explained by a complex interaction among the impact of Confucianism throughout the history of China, the intellectual preferences of the ruling classes of Imperial China, and the historical lack of a developed merchant class that would need to protect innovations while engaging in trade.<sup>18</sup> Intellectual property

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16. Striking examples of Chinese inventiveness include: gunpowder, paper, porcelain, the magnetic compass, oil refining, the chain-drive transmission, the segmental arch bridge, iron casting, the differential gear, the piston bellows, deep drilling, and the stirrup. Rudi Volti, TECHNOLOGY, POLITICS, AND SOCIETY IN CHINA 15 (1982) (citing Joseph Needham, *Science and China's Influence on the World* in Owen Dawson, THE LEGACY OF CHINA 234-308 (1971)).

17. WILLIAM P. ALFORD, TO STEAL A BOOK IS AN ELEGANT OFFENSE: INTELLECTUAL PROPERTY LAW IN CHINESE CIVILIZATION (1995); for a concise discussion of the roots of the Chinese legal system as compared to the U.S. legal system, see The Honorable Sam Hanson, *The Chinese Century: An American Judge's Observations of the Chinese Legal System*, 28 WM. MITCHELL L. REV. 243, 249-252 (2001).

18. American legal commentators often attribute the absence of the concept of intellectual property in Chinese society to Confucianism, the prevalent philosophy that influenced China throughout much of its history. See, e.g., John R. Allison & Lianlian Lin, *The Evolution of Chinese Attitudes Toward Property Rights in Invention and Discovery*, 20 U. PA. J. INT'L ECON. L. 735, 743-744 (1999); Jill Chiang Fung, *Comment, Can Mickey Mouse Prevail in the Court of the Monkey King? Enforcing Foreign Intellectual Property Rights in the People's Republic of China*, 18 LOY. L.A. INT'L & COMP. L.J. 613, 615 (1996); Patrick H. Hu, "Mickey Mouse" in China: *Legal and Cultural Implications in Protecting U.S. Copyrights*, 14 B.U. INT'L L.J. 81, 104 (1996); Peter K. Yu, *Piracy, Prejudice, and Perspectives: An Attempt to Use Shakespeare to Reconfigure the U.S.-China Intellectual Property Debate*, 19 B.U. INT'L L.J. 1, 17 (2001); 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, 8-10 (1997); Alford, *supra* note 17. However, it seems that attributing the failure of an intellectual property concept in China to the dominance of Confucianism in Chinese thought creates an overly-simplistic analysis. See Volti, *supra* note 16. Rather, it may be appropriate to also consider that the isolationist attitudes that dominated the governmental policy through most of Imperial China eliminated the development of a merchantile economy of the type that created the necessity for patents and other intellectual property rights in Europe. For excellent discussions of the development of patents in the west, see F.D. Prager, *The Early Growth and Influence of Intellectual*

laws in China thus did not evolve organically with Chinese society but rather were exported, often through trade-associated political pressure, from the West.<sup>19</sup>

The current Chinese patent law was enacted in its basic form in 1984.<sup>20</sup> The original version of this law received strong criticism for providing inadequate protection of IPRs in theory and in practice, as the law was poorly enforced and penalties to patent infringers were extremely small by Western standards.<sup>21</sup> Subsequent changes to China's intellectual property laws were largely influenced by external pressures, most notably and significantly from the U.S.<sup>22</sup> Yet, the criticisms of Chinese law structure and enforcement continue despite significant

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*Property*, 34 J. PAT. OFF. SOC'Y 106, 107-108 (1952); M. Frumkin, *The Origin of Patents*, 27 J. PAT. OFF. SOC'Y 143 (1945).

19. See Zuolong Wu, *Pharmaceutical Patent in the PR China: Adjustment in Public Health Concern 9-13* (Autumn 2002) (unpublished master's thesis, Lund University), available at [http://www.jur.lu.se/Internet/English/essay/Masterth.nsf/0/962236EAFDDF60F3C1256C2300545401/\\$File/xsmall.pdf?OpenElement](http://www.jur.lu.se/Internet/English/essay/Masterth.nsf/0/962236EAFDDF60F3C1256C2300545401/$File/xsmall.pdf?OpenElement).

20. The first modern Chinese patent law actually dates to 1950 and the issuance of the "Provisional Regulations on the Protection of the Invention Right and the Patent Right." Louis S. Sorell, *A Comparative Analysis of Selected Aspects of Patent Law in China and the United States*, 11 PAC. RIM L. & POL'Y J. 319, 321 (2002). However, this law was hardly recognizable as a modern patent law, as it did not guarantee the right to exclude others from the use of patented technology. See Chen, *supra* note 18, at 12. Not until the "Four Modernizations" following the Cultural Revolution, was a new attempt made to create a patent system in China. L. Harrington, *Recent Amendments to China's Patent Law: The Emperor's New Clothes?*, 17 B.C. INT'L COMP. L. REV. 337, 343 & n. 35 (1994). In the early 1980s, the Chinese government sent numerous envoys with legal, scientific, and political backgrounds abroad to study the patent laws of various developed nations. *Id.* at 345. Based largely on the information gathered by these envoys, China enacted a basic patent law in 1984. *Id.*

21. See generally Richard J. Ansson, Jr., *International Intellectual Property Rights, the United States, and the People's Republic of China*, 13 TEMP. INT'L COMP. L.J. 1, 10-11 (1999); Glen R. Butterton, *Pirates, Dragons and US International Property Rights in China: Problems and Prospects of Chinese Enforcement*, 38 ARIZ. L. REV. 1081, 1093-1105 (1996); Jeffrey W. Berkman, *Intellectual Property Rights in the P.R.C.: Impediments to Protection and the Need for the Rule of Law*, 15 UCLA PAC. BASIN L.J. 1, 14-37 (1996).

22. For discussions of the U.S. pressures on China that forced changes to Chinese intellectual property laws in 1992, 1994, and 1996, see Frank J. Garcia, *Americas Agreements—An Interim Stage in Building the Free Trade Area of the Americas*, 35 COLUM. J. TRANSNAT'L L. 63, 128 n.324 (1997) (explaining that "Special 301 . . . requir[es] the United States Trade Representative to identify countries which deny adequate and effective protection of intellectual property rights, and designate those countries for investigation and possible retaliation . . ."); see also Dennis S. Fernandez, *China's IP Is Not Entirely Out of the Haze Yet*, 10 No. 6 INTELL. PROP. STRATEGIST 1 (2004); Naigen Zhang, *Intellectual Property Law Enforcement in China: Trade Issues, Policies and Practices*, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 63, 72 (1997).

modification of legal practices concerning IPRs.<sup>23</sup> Nevertheless, because of the significant influence of the U.S. in shaping Chinese IPR policy, China Patent Law has many elements that should be familiar to U.S. practitioners.<sup>24</sup>

Despite the current structural and enforcement problems involving IPRs, China's intellectual property law in general and patent law in particular have evolved tremendously within a relatively brief period of time.<sup>25</sup> It is important to realize that—particularly in the case of patent law—the current structure of intellectual property law in China is of foreign origin.<sup>26</sup> It will take time before these laws, which not only did not develop organically within the Chinese legal system but also conflict with thousands of years of cultural history, are integrated into modern Chinese legal and economic culture. Nevertheless, there are indications that Chinese businesses are adopting a new way of doing business that uses intellectual property laws strategically rather than simply violating the intellectual property rights of foreign businesses. One such area of business is in the Chinese pharmaceutical industry. The changes in the attitude toward patent law in China can be seen in the ongoing attempt of twelve Chinese pharmaceutical companies to invalidate Pfizer Corp.'s Viagra patent in China.<sup>27</sup>

### III. CHINA'S PROGRESS ON THE ROAD TO IPRS IS EXEMPLIFIED IN PHARMACEUTICALS

The protection of intellectual property rights is the most extensive in the West, especially in the U.S.<sup>28</sup> In the United Kingdom and in its legal cousin the United States, as well as in continental Europe, patent and other intellectual property laws developed organically within the respective legal systems rather

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23. See Assafa Endeshaw, *A Critical Assessment of the U.S. – China Conflict*, 6 ALB. L.J. SCI. & TECH. 295, 309-35 (1996).

24. See generally, Louis S. Sorell, *A Comparative Analysis of Selected Aspects of Patent Law in China and the United States*, 11 PAC. RIM L. & POL'Y J. 319, 321 (2002).

25. Endeshaw, *supra* note 23, at 299 (noting that China adopted the entire gamut of intellectual property rights laws in a decade).

26. See Allison & Lin, *supra* note 18.

27. Audra Ang, *Chinese Companies Hoping to Copy Viagra*, BOSTON GLOBE, Dec. 6, 2002, at A40, available at 2002 WLNR 2594224.

28. See generally, Ruth Gana Okediji, *Copyright and the Public Welfare in Global Perspective*, 7 IND. J. GLOBAL LEGAL STUD. 117 (1999); Dru Brenner-Beck, *Do As I Say, Not As I Did*, 11 UCLA PAC. BASIN L.J. 84 (1992).

than being imposed from outside legal systems.<sup>29</sup> It is not coincidental that collectively, citizens of these countries realize substantial benefits from the enforcement of IPRs—the perceived value of IPRs provided the impetus for those very laws that protect the economic interests in those intangible rights.<sup>30</sup>

In contrast to the West, citizens of the PRC are only beginning to realize the economic benefits that attach to IPRs. With the reforms of the 1990s, the winds of economic change are bringing an awareness of the value of intellectual property.<sup>31</sup> Initially, as seen by the rampant counterfeiting and piracy of copyrights and trademarks, many Chinese businesses recognized only the value of intellectual property that belonged to foreign investors.<sup>32</sup> Increasingly, however, Chinese businesses recognize the benefit to their own economic interest that can be gained through the use of intellectual property laws.

To see the effect of this trend, consider China's pharmaceutical industry. PriceWaterhouseCoopers estimated that in 2000, China's pharmaceutical industry was worth \$28.2 billion (approximately 2.8 percent of GDP).<sup>33</sup> In 2002, China's pharmaceutical industry experienced a 15.5 percent rate of growth, with a 22 percent growth in profits.<sup>34</sup> The central government is

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29. See Frumkin, *supra* note 18, at 144-48; Prager, *supra* note 18, at 107-08.

30. The early concept of intellectual property in Europe, dating to the sixteenth century, coincided with the movement of skilled artisans from one locale to another throughout the Continent, often attracted by a local government or monarch, and the need of these artisans to protect the secrets of their trade. See Prager, *supra* note 18 at 108. It seems clear that the concept of intellectual property would not have been so important at the time were it not for the increase in trade and the merchant class during the European renaissance. See *id.*; see generally Frumkin, *supra* note 18.

31. See, e.g., Jeffrey W. Berkman, *Intellectual Property Rights in the P.R.C.: Impediments to Protection and the Need for the Rule of Law*, 15 UCLA PAC. BASIN L.J. 1, 16-17 (1996); Jianshang Yu, *People's Republic of China: Protection of Intellectual Property in the P.R.C.: Progress, Problems, and Proposals*, 13 UCLA PAC. BASIN L.J. 140, 140 (1994); Naigen Zhang, *Intellectual Property Law in China: Basic Policy and New Developments*, 4 ANN. SURV. INT'L & COMP. L. 1, 1 (1997).

32. Daniel C.K. Chow, *Counterfeiting in the People's Republic of China*, 78 WASH. U. L.Q. 1 (2000); Anglea Mia Beam, *Comment: Piracy of American Intellectual Property in China*, 4 J. INT'L L. & PRAC. 335, 336 (1995).

33. Allan Zhang, *The Future of China's Pharmaceutical Industry* (2001), <http://www.pwc.com/extweb/newcolth.nsf/docid/4CE903FAD5FB1DF985256A31007820CB> (last visited Feb. 24, 2005).

34. China Industry Development Report, [http://www1.cei.gov.cn/ce/e\\_report/hy/yy.htm](http://www1.cei.gov.cn/ce/e_report/hy/yy.htm) (last visited Feb. 18, 2005) (summarizing China's Pharmaceutical Industry in 2003).

currently putting money into the pharmaceutical industry, specifically to encourage domestic research and development.<sup>35</sup> With increasing profits and opportunity at stake, the Chinese drug companies that once built businesses around pirating foreign-owned pharmaceuticals are now beginning to use intellectual property laws as a strategic tool.<sup>36</sup> This shift in business practice is significant because it demonstrates that the enforcement of IPRs can provide a profitable business environment for Chinese businesses. A recent example of this shift is the well-publicized invalidation of Pfizer's Chinese patent on Viagra by SIPO. While criticized extensively by U.S. businesses and the U.S. trade officials as a sign that China lacks the interest in enforcing intellectual property laws and in complying with TRIPS, the case really provides an important example of the growing acceptance of IPRs in Chinese business culture.

*A. The Case of Pfizer's Viagra Patent in China Draws Criticism from the International Community*

While official reports of Chinese patent cases and administrative actions are often not published<sup>37</sup> and are therefore difficult to obtain, the progress of Pfizer's recent high-profile troubles with their Chinese patent on Viagra suggest that Chinese patent law is well on its way to comporting with international standards.

1. The invalidation of Pfizer's Viagra patent.

On May 13, 1994, Pfizer submitted an application for a patent entitled "Pyrazolopyrimidinones for the treatment of impotence" with the China SIPO.<sup>38</sup> On that same day, Pfizer submitted patent applications of the same name with, *inter alia*, the United States Patent and Trademark Office (U.S. PTO)<sup>39</sup> and the European

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35. China Internet Information Center, *China's Pharmaceutical Industry Gets Major Push*, Apr. 24, 2002, [http://service.china.org.cn/link/wcm/Show\\_Text?info\\_id=31451&p\\_qry=pharmaceutical](http://service.china.org.cn/link/wcm/Show_Text?info_id=31451&p_qry=pharmaceutical).

36. Yu, *supra* note 7.

37. See American Embassy in China, *IPR: Patent*, <http://www.usembassy-china.org.cn/ipr/patent.html> (last visited Nov. 28, 2005).

38. China patent application number 94,192,386, publication number 1,124,926 (filed May 13, 1994), available at [http://www.sipo.gov.cn/sipo\\_English/zljs/default.htm](http://www.sipo.gov.cn/sipo_English/zljs/default.htm).

39. U.S. Patent Application No. 549,792 (filed May 13, 1994).

Patent Office.<sup>40</sup> Pfizer considered these applications to be the basic patents covering the male erectile dysfunction drug Viagra;<sup>41</sup> however, none of the applications claimed the invention of sildenafil citrate, the drug's active ingredient. Instead, the applications claimed the use of this previously-known compound and its close variants for the preparation of a medical treatment for erectile dysfunction in a male animal.<sup>42</sup>

The State Drug Administration (SDA) approved Viagra for use in China on July 2, 2000.<sup>43</sup> The pre-patent version of the drug was marketed in China under the Chinese-language brand name Wan Ai Ke after a four-year wait for approval.<sup>44</sup> Access to the drug was limited to prescriptions from senior physicians in hospital urology departments, and dispensing was restricted to hospital pharmacies.<sup>45</sup> The drug was produced entirely at a pharmaceutical factory in Dalian, a city in Northeast China's Liaoning Province, and distributed exclusively by a local company, CNCN.<sup>46</sup>

The promise of the potential Chinese market for Viagra attracted the attention of local drug manufacturers, both legitimate and counterfeit. By May of 2000, a "well-known but unidentified" pharmaceutical company in China's Guangdong Province was manufacturing sildenafil citrate, the active ingredient in Viagra.<sup>47</sup> The company (presumably) relied upon the disclosures Pfizer made to the China SIPO in applying for a sildenafil citrate patent as a foundation for their research and development,<sup>48</sup> and

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40. European Patent Office No. EP 0 702 555 B1 (filed May 13, 1994).

41. In press releases from Pfizer and reports from the press, this patent has been referred to as Pfizer's "Viagra patent."

42. U.S. Patent No. 6,469,012 B1 (filed May 13, 1994) (issued Oct. 22, 2002); European Patent Office No. EP 0 702 555 B1 (filed May 13, 1994).

43. *China Grants Pfizer Patent for Viagra*, CHINA ONLINE, June 7, 2001, available at LEXIS, News Library.

44. Phelim Kyne, *Pfizer Patent on Viagra in China is Scrutinized During Hearings*, ASIAN WALL ST. J., Sept. 5, 2002, at M8.

45. Shi Pengyun, *Viagra No Longer Hard to Get*, CHINA DAILY, Feb. 7, 2002, available at [http://www.chinadaily.com.cn/en/doc/2002-02/07/content\\_105885.htm](http://www.chinadaily.com.cn/en/doc/2002-02/07/content_105885.htm).

46. *Id.*

47. *More to Love: Chinese Co. Creates Viagra Substitute*, CHINA ONLINE, May 23, 2000, available at LEXIS, News Library. This company is likely The Biochemical Pharmaceutical Factory of Zhuhai SEZ, listed as applicant of a patent application number 00804991 entitled "Process for preparing sildenafil, and troche which comprises sildenafil and apomorphine and its prep," dated June 8, 2000 and published February 26, 2003.

48. The China SIPO database lists "Pfizer Research And Development Co., N. V. / S. A." as the applicant of a patent entitled "Process for preparing sildenafil," application

developed a method of extracting and synthesizing sildenafil citrate that differed from the method claimed by Pfizer, and applied for its own patent with the China SIPO.<sup>49</sup> While this “Guandong Viagra” was required to undergo clinical trials before it could be sold commercially,<sup>50</sup> pressures on Viagra market share increased through the prevalence of counterfeit drugs sold in sex-shops, airports, and pharmacies throughout China.<sup>51</sup> Pfizer was able to combat some of the market pressure by entering into agreements with the Chinese government to combat counterfeit pharmaceuticals<sup>52</sup> and by securing an expansion of the official channels through which Viagra could be distributed.<sup>53</sup>

Pfizer received a “Notification to Grant Patent” from the China State Intellectual Property Office (SIPO) in early June, 2001.<sup>54</sup> The final patent was issued on September 19, 2001.<sup>55</sup> That same day, a group of twelve Chinese drug companies petitioned the Patent Reexamination Board to invalidate Pfizer’s patent.<sup>56</sup>

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number 97113261 dated June 13, 1997 and published December 12, 1997. See <http://www.sipo.cn/English>.

49. *More to Love*, *supra* note 47.

50. *Id.*

51. See Shi, *supra* note 45 (quoting the chief physician in urology at the First Hospital Attached to Peking University as stating, “all medicine with the name ‘Viagra’ for sale in drugstores are fake”); *China Passes Law to Combat Counterfeits*, CHEMICAL BUS. NEWSBASE, Sept. 4, 2002, at P10, available at 2002 WL 26164177; Kyne *supra* note 44 (noting that numerous counterfeit versions of Viagra sold at sex-oriented shops and at airports under the name “Weige” or “great man”); Ang, *supra* note 27 (citing the official Xinhua News Agency statistic that after six months on the market, some 90 percent of Viagra pills sold in Shanghai were counterfeit).

52. *Pfizer Signs Agreement with Shanghai Government to Enhance Protection of Patients*, Pfizer Inc. Press Release May 18, 2004, available at [http://www.pfizer.com/are/news\\_releases/2004pr/mn\\_2004\\_0518.html](http://www.pfizer.com/are/news_releases/2004pr/mn_2004_0518.html) (announcing the signing of a memorandum of understanding that allowed Pfizer to provide Chinese officials with, *inter alia*, anti-counterfeiting training).

53. See Shi, *supra* note 45

54. *China grants Pfizer patent for Viagra*, *supra* note 43.

55. Kyne *supra* note 44.

56. *Id.* There are notable discrepancies regarding the actual number of Chinese pharmaceutical companies that initiated or participated in the re-examination petition against the Pfizer patent. The reported number ranges from “over ten” (Delia Liu, *China Drug Cos Tie Up to Make Viagra Variant After Pfizer Loses Patent*, XINHUA FIN. NETWORK (XFN) NEWS, AUG. 5, 2004) to twelve (*Id.*; Ang, *supra* note 27; Guo Nei, *Viagra Patent Found Invalid*, CHINA DAILY, July 9, 2004, available at [http://www.chinadaily.com.cn/english/doc/2004-07/09/content\\_346788.htm](http://www.chinadaily.com.cn/english/doc/2004-07/09/content_346788.htm) to thirteen (*Pfizer—China challenges Viagra patent, loses US appeal against Apotex*, CHEMICAL BUS. NEWSBASE, Feb 13, 2003, at P31) to “up to 15” (*China’s IP officials still considering appeal against Pfizer’s Viagra patent*, XINHUA FIN. NETWORK (XFN) NEWS, Apr. 13,

Under Chinese law, once an announcement of a grant of patent rights is made, any interested entity or individual can petition the Patent Reexamination Board to reexamine the patent and declare the patent invalid.<sup>57</sup> The challenging coalition included Hongtaomao Pharmaceutical Co. Ltd., Lianxiang Pharmaceutical Co. Ltd.,<sup>58</sup> and Shuanglong Hi-tech Development Co. Ltd.<sup>59</sup> Some reports indicated that the mid-size companies had been refused patent protection for their own erectile-dysfunction drugs with a chemical composition similar to Viagra.<sup>60</sup> The strategy to challenge the patent in the Patent Reexamination Board, rather than to simply counterfeit the drug or otherwise infringe the patent, was a new approach to competing with foreign products. The relatively small Chinese pharmaceutical companies filing the re-examination petition view the procedure as an opportunity to “leapfrog” the long and costly research, development, and approval process that is required to bring a new drug to market.<sup>61</sup> According to a

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2004) to “more than 20” (*Pfizer Asks[sic] the Patent of Viagra*, SINOCAST CHINA BUS. DAILY NEWS, Dec. 4, 2002, at 8).

57. Zhonghua Renmin Gongheguo Zhuanli Fa [Patent Law of the People’s Republic of China] 12 P.R.C. LAWS 173 (adopted Aug. 25, 2000) [hereinafter China Patent Law], Art. 45 (“Where, starting from the date of the announcement of the grant of the patent right by the patent administration department under the State Council, any entity or individual considers that the grant of the said patent right is not in conformity with the relevant provisions of the Law, it or he may request the Patent Reexamination Board to declare the patent right invalid.”). The Patent Reexamination Board is created under Art. 41 of the China Patent Law (“The patent administration department under the State Council shall set up a Patent Reexamination Board. . . .”) and has sole jurisdiction over challenges to patent invalidity. The panel consists of three to five members, where five members are used if the case has great impact on China or abroad, involve important or complex legal issues, or involves large economic interests. Haitao Sun, *Note, Post-Grant Patent Invalidation in China and in the United States, Europe, and Japan: A Comparative Study*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 273, 288 (2004). The acceptable grounds for initiating a reexamination procedure are set-out in Implementing Regulations of the China Patent Law, Rule 64(2) (2001).

58. Kyne, *supra* note 3.

59. Duan Hongqing et al., *China Revokes Viagra Patent*, CAIJING ENGLISH NEWSLETTER, July 22, 2004, available at <http://www.caijing.com.cn/English/2004/040720/040720viagra.htm>.

60. Kyne, *supra* note 44; Shi, *supra* note 45. It is, however, unclear what is meant by this statement in the press. Pfizer’s Chinese patent did not protect the composition of Viagra, only the “use” of the drug sildenafil citrate for the treatment of male erectile dysfunction. Thus, the scope of the patent reportedly applied for by these companies is uncertain and a reliable report on this point cannot be located.

61. Kyne, *supra* note 44 (citing comments made by Cui Xiaoguang, president of the legal firm Beijing Sanyou Intellectual Property Agent Ltd., “If you completely imitate foreign medicines, it will save you a lot of money in obtaining the approval of medicine

statement from Lianxiang Pharmaceutical, the basis for the challenge to Pfizer's patent was the patent's ability to meet the novelty requirement under China's patent law.<sup>62</sup>

On July 7, 2004, the Patent Reexamination Board announced its decision to invalidate Pfizer's Viagra patent.<sup>63</sup> A full written decision was not released at that time.<sup>64</sup> However, one Chinese news source reported the language released by the Patent Reexamination Board at the time the Pfizer decision was announced:

In view of the technical descriptions in the specifications of the disputed patent and available technologies in the field concerned, it is impossible to confirm that the compound can cure or prevent erectile dysfunction of male animals without the creative labor of technical personnel in the filed concerned. Therefore, the technical openness in the patent specification is incompatible with the claims to rights, i.e. the disputed patent does not conform to the provisions in Clause 3 of Article 26 of China Patent Law. Therefore, the patent is declared invalid.<sup>65</sup>

Such assertions concerning the Patent Reexamination Board's language are in accord with the reports from other sources.<sup>66</sup>

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because you have some [foreign] data . . . so you may get the approval from the drug administration without much investment. These small companies don't want to spend much money, and hope the patent will be declared null and void.”).

62. See *Chinese Companies Challenge Viagra Patent*, *TAIPEI TIMES*, Dec. 9, 2002, at 12, available at <http://www.taipeitimes.com/News/worldbiz/archives/2002/12/09/186551>. For a discussion of the meaning of “novelty” under China Patent Law, see *infra* notes 153–157 and accompanying text.

63. Gardiner Harris, *Pfizer Reports China has Lifted its Viagra Patent*, *N.Y. TIMES*, July 8, 2004, at C1. Invalidated patents are deemed non-existent from the beginning, as if the patent were never issued. China Patent Law, *supra* note 57, Art. 47.

64. Harris, *supra* note 63.

65. Stone Xu, *An In-depth Look at Viagra's Abrupt Change of Fate in China*, *CHINA IP (HURRYMEDIA)*, Sept. 28, 2004 (on file with author) (quoting the No. 6228 Invalidity Claim Decision of the Patent Reexamination Board). Clause 3 of Article 26 of China Patent Law (2000) states: “The specification shall describe the invention or utility model in a manner sufficiently clear and complete so that a person skilled in the relevant field of technology can accurately produce it. . . .” China Patent Law, *supra* note 57.

66. E.g., Paul Mooney, *China challenging drug patents*, *THE SCIENTIST*, Aug. 20, 2004, <http://www.biomedcentral.com/news/20040820/02> (stating that a Chinese-language document on SIPO's web site stated that the Patent Reexamination Board revoked Pfizer's patent for insufficient disclosure, indicating that the patent application had failed to accurately explain the use of Viagra's key ingredients); Liu Li, *Patent on Viagra Faces Challenge*, *CHINA DAILY*, Sept. 29, 2004, available at [http://www.chinadaily.com.cn/English/doc/2004-09/29/content\\_378513.htm](http://www.chinadaily.com.cn/English/doc/2004-09/29/content_378513.htm) (reporting that the Patent Reexamination Board held the patent to be invalid because it did not conform to the patent application

According to Cao Jinyan, Vice President of the Patent Research Development Center of SIPO, Pfizer failed to fulfill the disclosure requirements in the patent application; thus, the invention could not be reproduced by experts based solely on the information provided in the patent application.<sup>67</sup>

Pfizer filed a petition for reconsideration directly with the SIPO on September 8 and an appeal of the Patent Reexamination Board's decision with the Beijing First Intermediate People's Court on September 28.<sup>68</sup> Pfizer claimed in its appeal that the Patent Reexamination Board unfairly applied a higher disclosure standard for the patent application during reexamination than was in effect at the time Pfizer submitted the application.<sup>69</sup> Pfizer has the right for one additional appeal to the High People's Court if the decision of Patent Reexamination Board is not reversed at the intermediate court level.<sup>70</sup> Each appeal could take up to three

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disclosure requirements under China Patent Law, Art. 26 (2000)); Ostrow, *supra* note 6 (reporting that the Patent Reexamination Board had determined that Pfizer had not provided full documentation in the patent application showing that Viagra's key ingredient sildenafil citrate was the primary factor in preventing erectile dysfunction).

67. Mooney, *supra* note 66.

68. Phelim Kyne, *Pfizer To File China Viagra Appeal Tue*, DOW JONES CHINESE FIN. WIRE, Sept. 28, 2004. The decision of the Patent Reexamination Board is subject to judicial review by the First Beijing Intermediate People's Court. PETER FENG, INTELLECTUAL PROPERTY IN CHINA 245 (2d ed. 2003). The court reviews Patent Reexamination Board decisions *de novo* and the Patent Reexamination Board has the burden of proof to demonstrate that its invalidation decision was proper. *See* Hanson, *supra* note 17 at 251; Albert P. Melone, Judicial Independence in Contemporary China, 81 JUDICATURE 257, 258 (1998). The party seeking judicial review must file the appropriate petition within three months of the PRD decision. Patent Law, Art. 46, 12 P.R.C. LAWS 173 (adopted Aug. 25, 2000). The court will uphold the decision of the Patent Reexamination Board if: (a) the evidence relied upon is conclusive; (b) the application of the law and regulations are correct; and (c) the legal procedures are complied with. Benjami Bai & Helen Chang, *Are Your Chinese Patents at Risk?*, INTELL. PROP. TODAY, Oct. 2004, available at [http://www.jonesday.com/pubs/pubs\\_detail.aspx?pubID=S1766](http://www.jonesday.com/pubs/pubs_detail.aspx?pubID=S1766).

69. Matthew Forney, *Patent Denied: Erectile Dysfunction is Big Business in China*, TIME MAG. ASIA, July 19, 2004, available at <http://www.time.com/time/asia/magazine/article/0,13673,501040719-662829,00.html>. Pfizer's argument on appeal seems to have been adopted for political purposes by the U.S. when commenting on its position on trade with China. U.S. Commerce Secretary Donald L. Evans stated in a speech given at the U.S. Embassy in Beijing that "[a]fter initially approving Viagra for sale in China, the Patent Review Board later applied a new law retroactively to deny Pfizer's patent." Press Release, State Department Press Releases & Documents (Jan 13, 2005), available at 2005 WL 58694563.

70. Zhonghua Renmin Gongheguo Fayuan Zuzhifa [Organic Law of the People's Courts of the People's Republic of China] [hereinafter Organic Law of the People's

years to complete;<sup>71</sup> during this time, Pfizer's patent would remain valid, bringing Pfizer within four years of its 2014 patent expiration date.

## 2. *The Fallout of the Viagra Patent Invalidation.*

Long before the Patent Reexamination Board's reexamination decision on the Viagra patent, Pfizer and the U.S. government positioned themselves to respond to the expected invalidation. In numerous statements to the press, both Pfizer and the U.S. government linked the future of American trade with the Chinese, as well as China's successful integration into the World Intellectual Property Organization (WIPO), with the outcome of the Pfizer case. For example, an unnamed "Western diplomat" was quoted in the *Asian Wall Street Journal* as stating, "I think it would have serious repercussions for the Chinese if the Pfizer patent was not upheld [and] it will really raise the question in the international community, drug makers as well as their governments, if SIPO is prepared and has the proper tools to make these decisions."<sup>72</sup> Trade officials from the U.S. also watched the Pfizer reexamination closely and "Deputy U.S. Trade Representative Josette Sheeran Shiner in November called the Chinese companies' challenge of Pfizer's Viagra patent a 'particularly troubling' example of China's questionable commitment to intellectual-property rights."<sup>73</sup>

The political posturing intensified upon SIPO's announcement of its decision to invalidate the patent. Richard Mills, the spokesman for the U.S. trade representative, told the *New York Times*, "It's difficult not to view this case within a pattern of intellectual property infringement. . . . [The United

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Courts], Art. 12 ¶ 1 (1983) ("In the administration of justice, the people's courts adopt the system whereby the second instance is the last instance"); Mooney, *supra* note 66. Pfizer will almost certainly be using its second appeal of right. From January 1989 to December 1998, the Beijing Intermediate People's Court has received 63 appeals of Patent Reexamination Board decisions to invalidate a patent; 56 of those cases have been decided and the court has decided against the Patent Reexamination Board in only nine of those cases. Jiang Zhipei, *Patent Litigation in China*, n.7 (Sept. 13, 1999), <http://www.chinaiprlaw.com/english/forum/forum4.htm#6>.

71. See Stone Xu, *An In-depth Look at Viagra's Abrupt Change of Fate in China*, CHINA IP (HURRYMEDIA), Sept. 28, 2004; Mooney, *supra* note 66.

72. Kyne, *supra* note 3.

73. Phelim Kyne, *China Overturns Pfizer's Patent for Viagra Drug*, ASIAN WALL ST. J., July 8, 2004, at A1.

States will] be discussing this and other intellectual property issues with the Chinese.”<sup>74</sup> One Western diplomat warned that the U.S. and the EU could retaliate for the SIPO decision with trade tariffs aimed at China’s domestic pharmaceutical industry.<sup>75</sup> The American Chamber of Commerce stated that “[t]he June 5, 2004, decision by SIPO to invalidate Pfizer Inc.’s use patent for Viagra. . . has caused great concern, extending beyond the pharmaceutical industry to the entire business community.”<sup>76</sup> Pfizer Chairman and Chief Executive Officer Henry McKinnell noted that regarding the decision, “[The company is] extremely disappointed. The basis of fair trade is respecting intellectual property.”<sup>77</sup> More importantly, McKinnell indicated that the decision “absolutely” could dissuade Pfizer from further investments in China.<sup>78</sup>

Despite the pronouncements of the U.S. trade office and the U.S. pharmaceutical industry, it is unclear whether the SIPO decision, even if upheld in appeal to the People’s Court, is indicative of anything but China’s progress toward adopting the intellectual property standards established by the WTO through TRIPS. Nevertheless, only a small handful of practitioners noted this significance in the Viagra patent reexamination. For instance, Gao Jun, a patent attorney with Duan & Duan Law Firm in Shanghai, noted that the Viagra patent reexamination indicated improvements in China’s patent protection.<sup>79</sup> “In years past, no one would even waste time on such legal battles. . . . Factories would rather start production of counterfeited or imitate medicines immediately.”<sup>80</sup> Professor Peter Yu of Michigan State University College of Law expressed a similar perspective, commenting that “the Viagra decision was exactly what the holders of IP rights should expect in a country making the transition to full compliance with the WTO agreements.”<sup>81</sup> A partner at the Shanghai office of a United Kingdom-based intellectual property law firm also pointed to the administrative challenges to drug patents in China as indicia of Chinese

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74. Harris, *supra* note 63, at C4 (quoting Richard Mills).

75. Kyne, *supra* note 73.

76. American Chamber of Commerce – China, *supra* note 10.

77. Lloyd-Smith, *supra* note 2.

78. *Id.*

79. Ang, *supra* note 27.

80. *Id.*

81. Yu, *supra* note 7.

companies using the patent system as a strategic business tool.<sup>82</sup>

The Chinese pharmaceutical industry was quick to take advantage of their initial legal victory in the Viagra patent dispute and revealed the next step in their strategy for competing against Pfizer for the erectile dysfunction drug market. Shortly after news of the SIPO decision became public, a group of seventeen Chinese pharmaceutical manufacturers announced their plan to establish a joint-stock company to produce an erectile dysfunction drug similar to Viagra.<sup>83</sup> By early October, 2004, the joint venture had established an office in Beijing and had invested the shareholders' capital in the new company.<sup>84</sup> The primary goal of this joint venture, according to Zhang Yucai, chairman of Tonghua Hongtaomao Pharmaceutical Co. Ltd., was to jointly promote the domestic "Viagra" while avoiding a price war with each other.<sup>85</sup> The joint venture had received authorization for the "Chinese Viagra" by the State Food and Drug Administration in October 2004 and is awaiting the required production license.<sup>86</sup> However, it is unlikely that the production license will be granted within a year:<sup>87</sup> the State Food and Drug Administration may choose to withhold a production license until the status of the Viagra patent is finalized by the courts.<sup>88</sup> If "Chinese Viagra" does eventually reach the market in China, it will be a formidable competitor for Pfizer because the Chinese alliance plans to sell their drug for 40 to 50 yuan per tablet, while the current price for Pfizer's Viagra in China is 99 yuan per tablet.<sup>89</sup>

While the Chinese pharmaceutical industry was enthusiastic about their initial victory in the SIPO over the Viagra patent, some

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82. Phelim Kyne & Leslie Chang, *Glaxo Gives Up Chinese Patent Amid Drug Makers' Challenge*, WALL ST. J., Aug. 19, 2004, at B6 (quoting attorney Douglas Clark of the law firm Lovells as stating, "The Chinese drug companies are starting to take the law seriously . . . trying to invalidate patents rather than just infringing them.").

83. Delia Liu, *China Drug Cos Tie Up to Make Viagra Variant After Pfizer Loses Patent*, XINHUA FIN. NETWORK (XFN) NEWS, AUG. 5, 2004.

84. Jia Hepeng, *Chinese Drug Firms Ally Against Pfizer*, BUS. WKLY. (CHINA DAILY), Oct. 18, 2004, [http://www.chinadaily.com.cn/english/doc/2004-10/18/content\\_383423.htm](http://www.chinadaily.com.cn/english/doc/2004-10/18/content_383423.htm).

85. *Id.*

86. *Id.*

87. *Id.* (citing Sun Mingjie, chairman of Guangzhou Viaman Pharmaceutical Co. Ltd.).

88. *Id.* (citing Wang Fei, a lawyer in the Beijing Huake Intellectual Property Firm).

89. Mooney, *supra* note 66.

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.<sup>90</sup> GlaxoSmithKline's patent, issued in July 2003,<sup>91</sup> was challenged by Chinese companies Shanghai Sunve Pharmaceutical Co. Ltd., which has a joint venture with Swiss-based Roche Holding AG, Chongqing Taiji Industry (Group) Co. Ltd., and Zhejiang Wanma Pharmaceutical Co. Ltd.<sup>92</sup> The challenge to Glaxo's patent, like the challenge to the Viagra patent, centered on the issues of novelty and inventiveness;<sup>93</sup> the Chinese plaintiffs asserted that some of the elements protected by the patent were already published in the public domain before the patent took effect.<sup>94</sup> The Chinese patent system requires absolute novelty with regards to publication of an invention for the issuance of a valid patent.<sup>95</sup> In addition, because China implemented a "first to file" system similar to the European patent systems rather than the unique "first to invent" priority system found in U.S. patent law, issues of novelty like the one that faced Glaxo are extremely difficult to circumvent.<sup>96</sup>

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90. Kyne & Chang, *supra* note 82.

91. Patent Application No. 98805686, covering 2 to 8 milligrams Rosiglitazone or its pharmaceutically-acceptable salts. Jia Hepeng, *Drugmakers Wrestle Over Medicine Patents*, CHINA DAILY, Aug. 17, 2004, available at [http://www.chinadaily.com.cn/English/doc/2004-08/17/content\\_366249.htm](http://www.chinadaily.com.cn/English/doc/2004-08/17/content_366249.htm).

92. *China Firms Challenge GlaxoSmithKline Drug Patent*, BUS. DAILY UPDATE (CHINA DAILY), Aug. 2, 2004, available at LEXIS, News Library; *Pharmaceutical Company Gives Up Chinese Patent on Popular Diabetes Drug*, DRUG WK., Sept. 10, 2004, at 523, available at LEXIS, News Library.

93. *Glaxo Withdraws Patent Defense in China*, CHINA BUSINESS PRESS, Sept. 8, 2004, available at <http://www.uscbp.com/NewsDetails.aspx?newsid=176>. Xu Gouwen, the lawyer who represented the Chinese drug companies, stated, "Glaxo's patent for rosiglitazone, the core intergradient [sic] of Avandia, has no creativity and no novelty [. . .] One year before Glaxo's patent application, as early as 1995, the *Journal of Clinical Pharmacology* published two articles in September and November issue [sic] respectively, elaborating on the effectiveness of 4-mg and 8-mg rosiglitazone for curing diabetes." *Id.*

94. Kyne & Chang, *supra* note 82.

95. China Patent Law, Art. 22 & 23 (2000). This requirement is in contrast to the U.S. system, which allows for a one-year grace period between the prior public disclosure in the United States and the patent application date. 35 U.S.C. § 102(a), (b) (2005).

96. China's "first to file" priority requirement is established in China Patent Law, Art. 22 & 23 (2000). The law does allow for a grace period in China Patent Law, Art. 24 (2000), whereby an invention "does not lose its novelty where, within six months of the filing date, one of the following events occurred: (1) where it was exhibited at a Chinese

Nevertheless, despite the dire predictions expressed in public by foreign corporations and Western diplomats, and especially despite Pfizer's threat to stop investing in China, Pfizer announced the establishment of a new regional headquarters in Shanghai and the founding of the Pfizer Investment Holding Company.<sup>97</sup> The formation of this holding company, with a registered capital of US\$175 million, signifies a significant commitment to the Chinese market by Pfizer.<sup>98</sup> The Chinese pharmaceutical market simply has too much growth potential for Pfizer to ignore.<sup>99</sup> And despite the rhetoric in the media, Pfizer must also clearly recognize that the China SIPO reexamination decision was neither *per se* unreasonable nor not out-of-step with the decisions reached by other foreign patent systems.

*B. "Chicken Little" Go Home: The Recent Petitions to Invalidate Pharmaceutical Patents Exemplify China's Progress Toward Acceptance of IPRs.*

Chinese companies are beginning to rely on patent law as part of their business strategy for addressing competition from foreign corporations.<sup>100</sup> The patent invalidation petitions against Pfizer and GlaxoSmithKline, both successful in different ways, exemplify this trend. While the two companies publicly deny any relationship between the two cases, pharmaceutical industry analysts believe that the two cases are similar in their role of encouraging more Chinese drug makers to utilize the patent laws rather than outright

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government exhibition, (2) where it was first made public in an academic or technological meeting; (3) where it was disclosed without the consent of the applicant." *Id.* Outside these narrow exceptions, it is very difficult to defend against a valid challenge on the basis of novelty in a first-to-file priority system. The prior art is either present or it is not, and the only defense to the challenge is found in asserting that the patent at issue does not read on the alleged prior art. In the U.S. "first to invent" system, within certain limits, the patentee has the additional defense of "swearing behind" the prior art—i.e. submitting proof that he first conceived of the invention and exhibited reasonable diligence between the time of conception and reduction to practice. 35 U.S.C. § 102 (g) (2005).

97. Hu Yan, *Pfizer China Takes Giant Step in Local Market*, CHINA DAILY, Oct. 30, 2004, available at 2004 WLNR 11949113.

98. *See id.*

99. Bruce Einhorn et al., *Go East, Big Pharma*, BUS. WK., Dec. 13, 2004, at 28.

100. Zhu Shen, *Unleash The Dragon*, PHARMACEUTICAL EXECUTIVE, Dec. 1, 2004, at 82 (citing Tony Chen, head of the China IP practice group in the Shanghai office of Paul, Hastings, Janofsky & Walker LLP).

infringement to expand domestic markets for generic medicines.<sup>101</sup>

The invalidation proceedings concerning Viagra and Avandia patents are partly the result of the rapid growth of the patent system in China.<sup>102</sup> It is currently estimated that 97 percent of China's pharmaceuticals are generic copies of foreign drugs.<sup>103</sup> Much of the copying of non-patented drugs began in the late 1980s and early 1990s, when China's patent protections were, in general, relatively weak and pharmaceutical inventions were not patentable, but foreign pharmaceutical companies began investing in China.<sup>104</sup> In that climate, Chinese drug makers invested in drug copying work;<sup>105</sup> but through the 1990s, patent protection became stricter in China, and in 2000, China revised its patent law to comply with WTO requirements. Now that China's patent laws are relatively strong and are largely consistent with the WTO standards, Chinese drug makers are faced with a choice among: patent infringement risks; loss of investment and product; and bringing reexamination petitions to invalidate the foreign-owned patents.<sup>106</sup>

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101. Jia, *supra* note 91. Hou Dakun, president of Beijing KevinKing Management Consulting Co Ltd is quoted as stating "[t]he number of cases will definitely increase, as more and more domestic drugmakers try to break the monopoly of the international pharmaceutical giants on compounds they are copying." *Id.* Both the Pfizer and GlaxoSmithKline cases arose because Chinese drug makers attempted to copy the drugs at issue before the patents on them were granted by developing either different ways to make the same—as the case with Viagra—or similar—as the case with Avandia—chemical compounds. *Id.*; see also notes 47–50 and accompanying text.

102. From 2002 to 2003, the number of patent applications in China grew by more than 20 percent; the China State Intellectual Property Office received 105,318 applications for inventions in 2003. ANNUAL REPORTS 2003, China State Intellectual Property Office, [http://www.sipo.gov.cn/sipo\\_English/ndbg/nb/ndbg2003/default.htm](http://www.sipo.gov.cn/sipo_English/ndbg/nb/ndbg2003/default.htm). For comparative purposes, the U.S. Patent & Trademark Office received 342,441 applications for utility patents in 2003, representing a growth of 2.4 percent over the number filed in 2002. See U.S. PAT. & TRADEMARK OFF., U.S. PATENT STATISTICS, CALENDAR YEARS 1963 – 2003, [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\\_stat.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf).

103. Jia, *supra* note 91.

104. See, e.g., *More transnational Firms Invest in China*, XINHUA NEWS AGENCY, Sept. 10, 1993, available at 1993 WL 12194406; *China: Joint Venture Construction Plans for \$130,000,000 Pharmaceutical Manufacturing Project, SmithKline Beecham (SB) (USA), China Natural Biological Products Corporation & Shanghai Institute of Biological Products (China)*, ESP-REP. ON OIL GAS & PETROCHEMICALS DEV. WORLD, Dec. 1, 1992, available at 1992 WL 2732585.

105. See Einhorn et al., *supra* note 99.

106. See Stone Xu, *An In-depth Look at Viagra's Abrupt Change of Fate in China*, CHINA IP (HURRYMEDIA), Sept. 28, 2004, available at [http://www.hurrymedia.com/jijia\\_new/news/2004-9-28-01.htm](http://www.hurrymedia.com/jijia_new/news/2004-9-28-01.htm).

In the cases of Viagra and Avandia, the local drug makers chose to try to invalidate the patents that would threaten their business. Considering the choices, the reexamination proceedings are the best alternative for both Chinese business and foreign investors. The decisions to invalidate the patents are not out-of-step with international IPR standards, and the early successes incentivize the Chinese companies to rely on the legal system as a part of their business strategy.<sup>107</sup> Such reliance is exactly the attitude that is required for the success of IPR protection in China and is consistent with the way IP-intensive industries conduct business in the U.S. and the EU.

The challenge to Pfizer's Viagra patent in China is not unique; the primary Viagra patent has faced several challenges and has been invalidated not only in China, but also in the United Kingdom<sup>108</sup> and the countries of the Andean Pact.<sup>109</sup> Only in Japan has it successfully weathered a direct validity challenge.<sup>110</sup> Certainly, the patent laws in all of these countries are somewhat different, but all meet the standards set by the WTO.<sup>111</sup> However, even if the patent laws were identical, the same facts may be applied to the law differently, depending on the legal traditions of each country. Nevertheless, the outcome of patent reviews in these other countries in which the Viagra patent has been challenged not only indicate that the invalidation decision of the China Patent Reexamination Board is not unreasonable, but also can indicate the likely outcome of Pfizer's appeal of that decision to the Beijing First Intermediate People's Court.

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107. See Scott Hensley, *Pfizer's Use Patent For Viagra Suffers Setback in Britain*, WALL ST. J., Nov. 11, 2000, at B2.

108. *Id.*

109. Tanja Sturm, *Andean Community Orders Ecuador to Suspend Pfizer Patent*, WMRC DAILY ANALYSIS, Nov. 18, 2002, available at 2002 WL 104062091; Tanja Sturm, *Andean Tribunal Lifts Sanctions Over Viagra Patent Dispute*, WMRC DAILY ANALYSIS, Sept. 16, 2002, available at 2002 WL 104031409; *No Patent Protection for Viagra in Peru*, MARKETLETTER, Sept. 9, 2002, available at 2002 WL 7180904; see *Viagra Patent Row*, CHEMISTRY & INDUS., Feb. 7, 2000, at 87; *Colombia: Pfizer Loses Viagra Patent Rights*, S. AM. BUS. INFO., Jan. 27, 2000, available at 2000 WL 7712696.

110. Press Release, Pfizer Pharmaceuticals Ltd. (China) (July 10, 2003), <http://www.pfizer.com.cn/htmls/edex/edex4-7.htm>.

111. Understanding the WTO: The Organization, Members and Observers (Dec. 11, 2005), [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm).

### 1. The Structure of the Viagra Patent.

The difficulties facing Viagra patents throughout the world are primarily the result of the complicated history of the development of the drug.<sup>112</sup> Pfizer originally developed and tested Sildenafil citrate for the treatment of heart disease. During clinical trials, Pfizer discovered the effectiveness of sildenafil citrate for the treatment of male erectile dysfunction.<sup>113</sup> A patent covering the compound sildenafil citrate would have provided the strongest protection for Viagra.<sup>114</sup> In the early 1990s, however, Chinese law did not grant patents on pharmaceuticals or other chemical compositions.<sup>115</sup> Further complicating the acquisition of this patent was the fact that the first novel use of sildenafil citrate was for hypertension and other cardiological or circulatory disorders.<sup>116</sup> Thus, Pfizer's patent had to be a "second use" patent—a type of patent not recognized by all countries.<sup>117</sup> By the time China's patent law allowed patent protection for pharmaceutical compounds, Viagra was no longer novel under Chinese patent law, even if it had been at the time Pfizer first applied for its use patent.<sup>118</sup>

Under China's current patent law, a "use" invention of a pharmaceutical compound or composition can be protected by an

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112. *U.S. Viagra Ruling Stiffens Pfizer Claims*, SHANGHAI DAILY, Nov. 8, 2002, reprinted in Lehman, Lee & Xu, *China E-ventions*, <http://www.chinalaw.cc/newsletter/patent/20030110.htm>.

113. Harris, *supra* note 63.

114. See discussion accompanying notes 119 through 133 *infra*; see also Wu, *supra* note 19, at 8.

115. American Embassy in China, Protecting Your Intellectual Property Rights (IPR) in China, <http://www.usembassy-china.org.cn/ipr/ovview.html> (last visited November 28, 2005). See, Wu, *supra* note 19, at 8.

116. *Lilly ICOS Ltd. v Pfizer Ltd. (No.1)*, [2001] F.S.R. 16, 234 – 35 (Ch D (Patents Ct)).

117. The countries of the Andean Community do not recognize the patentability of these so-called "second uses." According to Article 21 of Decision 486, Common Intellectual Property Regime of the Andean Community, "products or processes already patented and included in the state of the art . . . shall not be subject to new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent." PASCALE BOULET, CHRISTOPHER GARRISON & ELLEN 'T HOEN, DRUG PATENTS UNDER THE SPOTLIGHT: SHARING PRACTICAL KNOWLEDGE ABOUT PHARMACEUTICAL PATENTS (2003), available at [http://www.accessmed-msf.org/documents/patents\\_2003.pdf](http://www.accessmed-msf.org/documents/patents_2003.pdf). This decision has been interpreted by the Andean Tribunal of Justice as disallowing so-called second-use pharmaceutical patents in the countries of the Andean Community. *Id.*

118. *Id.*

“invention” patent, a type of patent that is roughly equivalent to a “utility patent” in the United States.<sup>119</sup> However, such a patent can be written only in the form of a preparation process; the reasoning is that when a new use as an active component of pharmaceuticals is discovered, the substance itself does not become novel.<sup>120</sup> Claims must be drafted in the form: “Use of sildenafil citrate in the preparation of pharmaceuticals against male erectile dysfunction,” but not in the form “Use of sildenafil citrate for treatment of male erectile dysfunction.”<sup>121</sup> The latter form is deemed a patent on a treatment for disease, a type of patent protection not recognized under the China Patent Law.<sup>122</sup> When drafted in the correct form, the use patent claim can be applied to a first- or second-use of pharmaceutical compound.<sup>123</sup>

In 1994, Pfizer applied for a Chinese patent for the use of sildenafil citrate in the treatment of erectile dysfunction. At the same time, it made similar applications in Japan, the European Union, and other countries.<sup>124</sup> Entitled “Pyrazolopyrimidinones for

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119. See Sorell, *supra* note 20 at 326. Under U.S. patent law, “utility patents” are those of a subject matter covered by 35 U.S.C. § 101. The categories of subject matter covered under § 101 are: process (a series of steps for carrying out a given task), machine (generally an apparatus containing moving parts), composition of matter (including chemical compositions and mixtures of substances), and manufacture (any human-made subject matter without moving parts). See 35 U.S.C. § 101 (2005). The vast majority (90 percent) of patents issued by the U.S. Patent & Trademark Office are utility patents. See U.S. PAT. & TRADEMARK OFFICE, UNITED STATES PATENT STATISTICS, CALENDAR YEARS 1963 – 2001, [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\\_stat.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf). Other types of patents under U.S. law are: design (35 U.S.C. § 171; see *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557 (Fed. Cir. 1998)) and plant (35 U.S.C. § 161, see *Imazio Nursery v. Dana Greenhouses*, 69 F.3d 1560 (Fed. Cir. 1995)).

120. See Zhang Qing-kui, *Patent Protection of Pharmaceutical Invention in China*, <http://www.cnpatent.com/main/main5/yibao.htm> (last accessed Nov. 8, 2005) (Zhang Qing-kui was the Director General of the Chemical Examination Department of the Chinese State Intellectual Property Office at the time this article was written).

121. *Id.* In contrast, the U.S. patent for Viagra directly claims the process of the treatment: “A method of treating erectile dysfunction in a male animal, comprising administering to a male animal in need of such treatment an effective amount of a compound of formula (I) . . .” Claim 1, U.S. Patent No. 6,469,012 (filed May 13, 1994) (issued Oct. 22, 2002).

122. China Patent Law, *supra* note 57, Art. 25 (2000).

123. See Zhang, *supra* note 120.

124. The EU patent EP0702555 entitled “Pyrazolopyrimidinones for the treatment of impotence” listed a number of patents in countries both within and outside of the EU as equivalent patents. Among these patents listed is the China patent publication number 1124926 entitled “Pyrazolopyrimidinones for the treatment of impotence.” Because this China patent is not available in translated form for comparison purposes, it is assumed

the treatment of impotence,” the patent application covered a class of compounds that includes sildenafil citrate.<sup>125</sup> The patent contained eleven claims; the relevant language of the only independent claim was worded as follows:

1.The use of a compound of formula (I) [diagram of the basic chemical structure and list of “R-groups”] or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man.<sup>126</sup>

This language complies with the requirements for a pharmaceutical use patent under China Patent Law.<sup>127</sup> The claim as written referred to hundreds of compounds.<sup>128</sup> Subsequent dependent claims in the patent application referred to claims on progressively smaller groups;<sup>129</sup> the final claim in the patent claimed the use of generic cGMP PDE<sub>v</sub> inhibitors.<sup>130</sup> The specification first disclosed the use of a general class of pyrazolopyrimidinones and equivalent salts, and then goes on to identify a “preferred group of compounds” within claimed Formula (I), a “more preferred group,” and a “particularly preferred group,” each containing a smaller subset of the previous

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that the scope of the EU patent and the China patent are the same. The U.S. patent of the title “Pyrazolopyrimidinones for the treatment of impotence,” it should be noted, has a broader claim scope than the EU patent of the same title but is not listed as an equivalent on the EU patent. It should also be noted that the author has located one media source that reported that the China patent had a scope narrower than the EU patent in that the China patent listed only sildenafil citrate in the claim language rather than the entire class of compounds termed pyrazolopyrimidinones. *See* Hongqing et al., *supra* note 59. (“Pfizer’s U.K. patent included more than 100 chemicals . . . . In the Chinese case, however, Viagra’s patent listed only one chemical, siladenafil [*sic*] citrate . . . .”). However, the claim scope suggested by this source seems unlikely for two reasons: first, the EU patent lists the China patent as an equivalent, and second, the title of the China patent clearly suggests the claim coverage of the class of pyrazolopyrimidinones, not only sildenafil citrate.

125. European Patent Office No. EP 0 702 555 B1 (filed May 13, 1994).

126. *Id.* at 5:29 – 6:11.

127. *See* Zhang, *supra* note 120.

128. *See* European Patent Office No. EP 0 702 555 B1 (filed May 13, 1994).

129. A “dependent claim” is one that refers to (or depends upon) some other, previously presented claim, while an independent claim stands alone without referring to any other claim. Under U.S. patent law, these claiming principles are governed by 35 U.S.C. § 112 (2005).

130. *Id.* For an explanation of “cGMP PDE<sub>v</sub> inhibitor,” *see* discussion *infra* note 134 and accompanying text.

group of compounds.<sup>131</sup> Reference is then made to “specially preferred individual compounds of the invention” which “include” nine named chemicals.<sup>132</sup> One of those named chemicals is sildenafil citrate.<sup>133</sup>

The compound sildenafil citrate is part of a subclass of pyrazolopyrimidinones known as PDE<sub>v</sub> inhibitors.<sup>134</sup> Briefly, the PDE<sub>v</sub> inhibitor is a compound that inhibits the formation of a category of PDE, or phosphodiesterase enzyme, that plays an important role in the relaxation of smooth muscle fibers.<sup>135</sup> The selective inhibition of cGMP PDE (cyclic Guanosine Monophosphate phosphodiesterase enzyme) leads to elevated levels of cGMP which, in turn, provide the basis for relaxation of smooth muscles fibers.<sup>136</sup> Smooth muscle fibers largely comprise the structure of the heart, and relaxation of these fibers is effective for the treatment of heart disease such as, *inter alia*, hypertension, angina, and congestive heart failure.<sup>137</sup> The relaxation of smooth muscle fibers in the penis is a critical step in the development of a penile erection and cGMP PDE inhibitors can effectively treat male erectile dysfunction.<sup>138</sup>

2. *Invalidity of Pfizer's Viagra Patent.* The challenge to Pfizer's Chinese patent emphasized the arguments used in *Lilly v. Pfizer* to invalidate the equivalent patent in the U.K. and then in the EU.<sup>139</sup> In the U.K. case, Lilly ICOS LLC challenged the

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131. *Id.*

132. *Id.*

133. *Lilly*, [2001] F.S.R. 16 at 215.

134. *See id.* at 207–14. (providing an excellent summary of the biochemistry and pharmacology of cGMP PDE inhibitors as related to the Viagra patent).

135. *Id.* at 210–211.

136. *Id.* at 211.

137. *Id.* at 214.

138. *Id.*

139. *See Case to Invalidate the Patent right of Viagra on Trial*, SANYOU IP NEWSLETTER (Beijing Sanyou Intellectual Property Agency, Beijing, P.R.C.) (Vol. 13, No. 4) (2002) (reporting that during the reexamination hearings at SIPO, the party making the request for the invalidation cited the following reasons: “1. the technical solution of the patent possessed neither novelty nor inventiveness as compared with the references they searched out; 2. the amendments to the claims went beyond the original disclosure of the specification; 3. House of Lords in England declared on June 17, 2002 that the patent right of Viagra filed by Pfizer Inc. to be invalid”) (on file with author); Duan Hongqing et al., *supra* note 59 (reporting that, according to Xu Guowen, the lead attorney for the Chinese pharmaceutical companies seeking the reexamination, the complaint “cited the same evidence that the British High Court used to strike down the Viagra patent”).

validity of Pfizer's U.K. patent on the basis of anticipation, obviousness, insufficiency, and added matter.<sup>140</sup> The anticipation argument was advanced on the basis of a single document published in April 1993;<sup>141</sup> the obviousness argument was founded on a number of documents, but three were relied upon most heavily.<sup>142</sup> The U.K. court that invalidated Pfizer's patent for obviousness, did not find that Pfizer's patent had been anticipated by prior art, and found the insufficiency and added matter arguments to be relevant only to the issue of claim construction.<sup>143</sup> The arguments presented to the U.K. court illustrate the evidence and arguments presented to the China Patent Reexamination Board by the parties seeking reexamination of the China Viagra patent. Similar arguments will almost certainly be made at Pfizer's appeal to the Beijing First Intermediate People's Court. Considering the current state of China's patent law, it seems likely that these arguments will be successful at the Intermediate Court and again at the Supreme People's Court if another appeal is made by Pfizer.<sup>144</sup> At the end of the long appeals process, it is likely that the courts will invalidate Pfizer's patent for lack of inventiveness under China Patent Law, Art. 22 ¶ 3 (2000).

(a) *Invalidity for Lack of Disclosure.* The initial decision of SIPO to invalidate the Viagra patent is difficult to assess because

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140. *Lilly*, [2001] F.S.R. 16 at 206.

141. *Id.* at 225 (identifying the document S.G. Korenman & S.P. Viosca, *Treatment of Vasculogenic Sexual Dysfunction with Pentozifylline*, 41 J. AM. GERIATRICS SOC. 363 (1993)).

142. These major documents were: J. Rajfer et al., *Nitric Oxide as a Mediator of Relaxation of the Corpus Cavernosum in Respect to Nonadrenergic, Noncholinergic Neurotransmission*, 362 N.E. J. MED. 90 (1992); K.J. Murray, *Phosphodiesterase VA Inhibitors*, 6 DRUG NEWS & PERSPECTIVES 150 (1993); Margaret Ann Bush, *THE ROLE OF THE L-ARGININE-NITRIC OXIDE-CYCLIC GMP PATHWAY IN RELAXATION OF CORPUS CAVERNOSUM SMOOTH MUSCLE*, Ph.D. Dissertation, University of California, Los Angeles (1993). *Lilly*, [2001] F.S.R. 16 at 206.

143. *Id.*

144. Chinese legal procedure allows courts on appeal to decide not only questions of law, as in U.S. appellate courts, but also questions of fact. Mo Zhang and Paul J. Zwier, *Burden of Proof: Developments in Modern Chinese Evidence Rules*, 10 TULSA J. COMP. & INT'L L. 419, 459 (2003). While in a parallel U.S. court action, the appellate court would send the case back to the U.S. Patent Office for a ruling in accord with its decision because it could not consider new arguments, appellate courts in China can consider both issues of law and of fact, as well as issues not raised in the original proceedings. Therefore, the Intermediate People's Court will likely consider the arguments of novelty and obviousness that were not ruled upon by the China SIPO but were raised by the parties seeking reexamination of the Pfizer patent.

an official opinion has not yet been released. However, considering the EU patent construction in conjunction with the comments of the U.K. court in *Lilly v. Pfizer* and the media reports from China following the SIPO decision, the SIPO Reexamination Board's invalidation does not appear unreasonable. The patent application did not disclose sildenafil citrate as the compound that was the active ingredient effective in treating erectile dysfunction; rather, the patent identified nine compounds, of which sildenafil citrate was one, as the "most preferred" for the practice of the invention. Such disclosure may run afoul of several requirements of China Patent Law. Principally, 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. This requirement is expanded upon by the Implementing Regulations which require that the description of the invention "[describe] in detail the optimally selected mode contemplated by the applicant for carrying out the invention or utility model. . ."<sup>145</sup> Media and industry reports out of China that claim the Patent Reexamination Board's decision to invalidate the patent was based on insufficient disclosure and an inability of the examiners to reproduce the invention suggest that Pfizer's application may not have met these requirements as established by China Patent Law, Art. 26 ¶ 3 (2000) and Implementing Regulations of the China Patent Law, Rule 18(5) (2001).

Under U.S. patent law, a similar requirement for disclosure in the patent application is that of "best mode."<sup>146</sup> The applicant for a U.S. patent must disclose in the specification, but not in the claims themselves, the "best mode" for the practice of the invention as defined by the subjective preference of the inventor at the time the

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145. Renmin Gongheguo Zhuanlifa Shishi Xize [Implementing Regulations of the Patent Law of the People's Republic of China (2001)], [hereinafter Implementing Regulations of the China Patent Law (2001)] Rule 18(8), [http://www.sipo.gov.cn/sipo\\_English/flfg/zlflfg/t20020327\\_33871.htm](http://www.sipo.gov.cn/sipo_English/flfg/zlflfg/t20020327_33871.htm).

146. 35 U.S.C. § 112 requires that the specification include the following: (i) a written description of the invention; (ii) the manner and process of making and using the invention; and (iii) the best mode contemplated by the inventor of carrying out the invention. 35 U.S.C. § 112 (2004); see also Mark S. Cohen, *Compliance with the Written description requirement in Biotechnology and Pharmaceutical Patents*, 805 PLI/PAT 9 (2004).

patent application was filed.<sup>147</sup> From the construction of the China Viagra patent, it would seem that the U.S. best mode requirement would be met, as sildenafil citrate was one of the compounds listed in the specification of the “most preferred.”<sup>148</sup> However, the U.S. best mode requirement is not as strict as the comparable China patent requirement, as U.S. law does not require a detailed description of the optimally selected model, i.e. the best mode.<sup>149</sup>

(b) *Invalidity for Lack of Novelty*. Even if the People’s Court were to find that the Patent Reexamination Board erred in the application of the disclosure requirements, Pfizer’s patent could be invalidated because it was either not novel or was obvious.<sup>150</sup> Under the China Patent Law, there are three requirements for patentability: novelty, inventiveness, and practical applicability.<sup>151</sup> According to reports from the Chinese legal community, Pfizer’s patent specification created a dilemma: arguments for the patent’s creativity undermined Pfizer’s assertion that the specification met the demands for openness. Conversely, Pfizer’s assertion that the demands for openness were met undermined evidence of the claim’s creativity.<sup>152</sup> Not coincidentally, in the U.K. case *Lilly v. Pfizer*, Lilly also claimed that the Pfizer patent failed to establish novelty and non-obviousness.<sup>153</sup> “Inventiveness” under China

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147. 35 U.S.C. § 112 (“The specification shall contain a written description of the invention . . . and shall set forth the best mode contemplated by the inventor of carrying out his invention.”).

148. There is no requirement in the U.S. patent system that the application “flag,” or otherwise draw attention to, the best mode, only that the best mode be included in the specification. In practice, the applicant for a U.S. patent will typically “bury” the best mode in the text of the specification so as not to draw attention to the preferences of the inventor.

149. 37 C.F.R. § 1.71(b), in expanding upon 35 U.S.C. § 112, provides that “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.” 37 C.F.R. § 1.71(b) (2004). This requirement is notably different from, and requires less specificity than, the disclosure required in Implementing Regulations of the China Patent Law, Rule 18(5) (2001) which requires a detailed description of the optimally selected mode.

150. Recall that the review by the People’s Court is *de novo* and therefore need not be limited to the issues addressed by the Patent Reexamination Board. Zhang and Zwier, *supra* note 144 at 459.

151. China Patent Law, *supra* note 57, Art. 22.

152. See Xu, *supra* note 65.

153. *Lilly*, [2001] F.S.R. 16 at 206.

Patent Law is analogous, but not identical, to the concept of “obviousness” under the U.S.<sup>154</sup> and U.K.<sup>155</sup> patent systems.

The U.K. court opinion in *Lilly v. Pfizer* lists a single publication that Lilly claimed anticipated Pfizer’s patent, thereby destroying novelty under the U.K. definition.<sup>156</sup> In China, a valid patent must possess novelty, where “[n]ovelty means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications in the country or abroad or has been publicly used or made known to the public by any means in the country. . . .”<sup>157</sup> If this listed publication did, in fact, disclose the invention claimed in the Pfizer patent, a court or other reviewing body must determine whether the Pfizer invention in the China patent application is novel as required under China Patent Law, Article 22 paragraph 2 (2000). However, based on the discussion of this publication in *Lilly v. Pfizer*, it is unlikely that a Chinese court would hold that this publication anticipates Pfizer’s claimed invention. Indeed, it may be the weakness of this anticipation argument based on the Korenman publication that resulted in the

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154. Sorell, *supra* note 20, at 326.

155. JOHN GLADSTONE MILLS, DONALD C. REILEY & ROBERT HIGHLEY, PATENT LAW BASICS § 20:2.3 (2004) [hereinafter MILLS, PATENT LAW BASICS]. The United Kingdom Patent Act § 3(3) defines the “inventive step” required for patentability: “An invention shall not be taken to involve an inventive step if it is obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue of section 2(2) . . .” “In cases attempting to invalidate patents as being obvious, courts in the United Kingdom rely on qualified expert witnesses to testify on whether a patent claim would have been ‘obvious to a person skilled in the art’ at the time the invention was first made.” MILLS, PATENT LAW BASICS at § 20:2.3. The U.K. standard for determining obviousness is similar to that used in the United States following *Graham v. John Deere Co.*, 383 U.S. 1, 14, 17 (1966). MILLS, PATENT LAW BASICS at § 20:2.3. The U.K. obviousness test is:

- (1) First the court identifies the inventive concept;
- (2) Next, the court will assume the mantle of the normally skilled but unimaginative addressee in the art at the relevant date and will impute to him what was at that date, common general knowledge in the art in question;
- (3) The court should then identify what, if any, differences exist between the matters cited as being “known or used” and the alleged invention;
- (4) Finally, the court has to decide whether viewed without knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they required any degree of invention.

*Id.* (citing *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, (1985) R.P.C. 59, 73).

156. *Lilly*, [2001] F.S.R. 16 at 225. Note, however, that the opinion stated in dicta that Lilly’s argument for anticipation failed. *Id.* at 260.

157. China Patent Law, *supra* note 57, Art. 22.

China SIPO invalidating Pfizer's patent on the basis of prior disclosure rather than novelty.

The anticipation argument in *Lilly v. Pfizer* failed on several levels, all of which would be relevant to a consideration of novelty under China Patent Law, Article 22 paragraph 2 (2000). First, Korenman's stated objective was to evaluate the use of the chemical pentoxifylline to treat erectile dysfunction in men.<sup>158</sup> Lilly claimed that pentoxifylline is a cGMP PDE inhibitor and that the publication describes the oral administration of such an inhibitor for the treatment of erectile dysfunction.<sup>159</sup> The U.K. court rejected this argument on the basis of expert testimony.<sup>160</sup> The court noted that pentoxifylline was not a PDE inhibitor. Even if it were a PDE inhibitor, it is not a selective cGMP PDE inhibitor as are the compounds claimed in Pfizer's patent.<sup>161</sup> Further, the court noted that while Lilly itself performed extensive tests aimed at proving pentoxifylline is an effective cure for erectile dysfunction, the Korenman publication did not prove this point.<sup>162</sup> For these reasons, the court held that the Korenman publication could not have anticipated Pfizer's invention.<sup>163</sup>

It should be noted that this decision in the U.K. was published in November 2000, before the China Viagra patent was issued or petitioned for reexamination. The Chinese pharmaceutical companies seeking the invalidation of the Viagra patent were undoubtedly aware of the U.K. court analysis of the novelty argument, yet they appear to have pleaded it despite its rejection under U.K. patent law. While a source that explains this strategy cannot be located, it seems likely that the Chinese pharmaceutical companies simply made the same arguments Lilly made to the U.K. courts in the hope that the China Patent Reexamination Board would view the Korenman publication differently.

(c) *Invalid because obvious.* Unlike the novelty challenge raised by Lilly in the U.K., the obviousness challenge is supported by a strong argument that convinced the U.K. Patents Court to invalidate Pfizer's U.K. patent and which would likely do the same

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158. *Lilly*, [2001] F.S.R. 16 at 258.

159. *Id.*

160. *Id.* at 259 – 60.

161. *Id.*

162. *Id.*

163. *Id.*

under China's patent law. In the opinion dismissing Pfizer's appeal of the Patents Court's decision in *Lilly v. Pfizer*, Lord Justice Aldous of the Supreme Judicature Court of Appeal summarized the court's position on obviousness in the Pfizer patent:

[A]s of the date of the Viagra patent, the product Viagra was known. It was also known that it was a selective cGMP PDEV inhibitor. It was also known that cGMP PDEV removed cGMP which caused or contributed towards an erection. It had also been suggested that such inhibitors could be useful in the treatment of impotence. Against that background this Court had to consider whether it was inventive to appreciate that Viagra, when taken orally, would cause or contribute to an erection. This Court concluded that it was not. The publication of the work done at the University of California was a crucial step in the Court's reasoning.<sup>164</sup>

China Patent Law requires an "inventive step" for a valid patent, where "an invention is considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art or the so-called 'notional skilled technician.'"<sup>165</sup> The requirement of invention is established in China Patent Law, Article 22 paragraph 3 (2000) and is typically explained in Chinese textbooks in the light of the European Patent Convention standards of non-obviousness.<sup>166</sup> The inventive step requires an "obvious difference in substantive or essential features compared to the prior art ('existing technology'), or that an ordinary or 'notional' technician skilled in the field of the invention cannot directly obtain from existing technology all necessary technical features which constitute the invention."<sup>167</sup> Pfizer's response to this requirement can be seen in the language used in its patent application.<sup>168</sup> Nevertheless, the U.K. courts were not persuaded by Pfizer's claims of inventiveness and for similar

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164. *Lilly IOCS Ltd. v. Pfizer Ltd.*, [2002] EWCA Civ 1, (CA (Civ Div)), available at 2002 WL 45115.

165. FENG, *supra* note 68, at 216 (citing Art. 56, EPC 1973).

166. *Id.* (noting the non-obviousness standard of the European Patent Convention).

167. *Id.*

168. For example, the specification of the Pfizer patent includes the language: "Unexpectedly, it has been found that these disclosed compounds are useful in the treatment of erectile dysfunction. Furthermore, the compounds may be administered orally, thereby obviating the disadvantages associated with i.c. administration." U.S. Patent No. 6,469,012 B1 (filed May 13, 1994) (issued Oct. 22, 2002), 1:59 – 66.

reasoning, and there is no reason to suppose that the Chinese courts would be so persuaded.

Where two or more published documents are referenced to establish the obviousness, or lack of inventiveness, of a claimed invention, reported Patent Reexamination Board cases suggest that there are several important factors for consideration:

- (1) how far apart the technological fields of the two or more reference documents are;
- (2) whether the technical problem resolved by the indispensable technical features of the invention is the same as that resolved by the corresponding prior art in the reference documents;
- (3) whether the invention arrived at by combining the relevant prior art in the reference documents is an idea that the notional skilled technician can arrive at through routine analysis, or an idea that can only be arrived at by unconventional thinking and overcoming long-standing technical prejudice; and
- (4) whether the result produced by such a combination can be expected by the notional skilled technician in the art.<sup>169</sup>

Certainly these factors are not binding on the Beijing First Intermediate People's Court, but<sup>170</sup> they undoubtedly provide indirect reference for the court. The opinion of the U.K. court in *Lilly v. Pfizer* makes clear that Pfizer's patent has little chance of surviving an appeal for lack of inventiveness. Of the three primary publications considered by the U.K. court, all are in the same technical field as the patent.<sup>171</sup> Indeed, two of the publications present research conducted by the research group of Nobel Laureate Professor Louis Ignarro at UCLA: Professor Ignarro served as the principle expert witness for Pfizer in both *Lilly v. Pfizer* in the U.K. and in the China Patent Reexamination Board hearings.<sup>172</sup> The publications further consider indispensable technical features of the Pfizer patent, especially in regards to the use of cGMP PDE inhibitors in the treatment of erectile

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169. FENG, *supra* note 68, at 218 – 19.

170. The Chinese legal system is a "civil law" system based on written statutes and, as such, court decisions do not constitute binding precedent but serve merely as guidance to courts. Jerome A. Cohen & John E. Lange, *The Chinese Legal System: A Primer for Investors*, 17 N.Y.L. SCH. J. INT'L & COMP. L. 345, 350 (1997).

171. *Lilly*, [2001] F.S.R. 16 at 258.

172. *See id.* at 226; Duan Hongqing et al., *supra* note 59.

dysfunction.<sup>173</sup> The U.K. courts concluded at the Patent's Court and the Appellate Court levels, as well as at the House of Lords, that the Pfizer patent was obvious. This conclusion can be analogized to the Chinese non-obviousness standard: an invention cannot receive a patent when the "invention [is] arrived at by combining the relevant prior art in the [publications was] [and is] an idea that the notional skilled technician can arrive at through routine analysis. . . and the result produced by such a combination can be expected by the notional skilled technician in the art."<sup>174</sup>

The U.K. patent system is well-established and is beyond criticism related to adherence to TRIPS standards. The U.K. courts invalidated the same patent that was invalidated by the Patent Reexamination Board in China, yet unlike China, the U.K. did not sustain any meaningful criticism for the decision. Clearly, the invalidation in China was for failure to meet China's disclosure requirements, an issue that was not relevant to the arguments in *Lilly v. Pfizer*. Nevertheless, it appears clear that, even without a body of Chinese case law with which to interpret the issue, Pfizer's Chinese patent could and should be invalidated for failure to meet the inventiveness requirement under China Patent Law, Art. 22 ¶ 3 (2000). Even if the Beijing First Intermediate People's Court reverses the Patent Reexamination Board invalidation under China Patent Law, Art. 26 ¶ 2 (2000), Pfizer is fighting a losing battle for its Viagra patent in China.

#### IV. CONCLUSION

It is clear that intellectual property rights in China are not afforded the same degree of protection as are IPRs in the United States, the EU, or even Japan. There is a great deal of criticism levied against China in this regard, especially from the United States. However, it is imperative that the world view the treatment of IPRs in China in the appropriate context. China, the oldest continuous civilization in the history of the world, has a cultural history reaching back several thousand years that does not include the concept of intellectual property. Not only were IPRs unnecessary in traditional Chinese culture because of the lack of a healthy merchant class and trade with foreigners, but IPRs

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173. See *Lilly*, [2001] F.S.R. 16 at 226 – 27.

174. FENG, *supra* note 68, at 216.

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conflicted with the Chinese concept of a harmonious society. From these roots, China has made dramatic progress in the implementation of laws to protect intellectual property.

However, to change a cultural collective mindset is necessarily a slow process and can only be accomplished where the changes result in a recognizable benefit. Through the 1990s, the U.S. was quick to force IPR laws on China, using the threat of trade isolation to push for the adoption of laws following the U.S. model. China adopted many of these laws to move into compliance with TRIPS and to gain entry into the WTO, and to avoid trade wars with the U.S. But economic domestic development in China lagged behind the growing international trade and foreign investment, and the IPR laws in China were used primarily to protect, or to attempt to protect, the IPRs of foreign businesses.<sup>175</sup> However, as domestic development in China grows, so do the potential benefits Chinese businesses can realize from the enforcement of IPR laws.

The current case of the invalidation of Pfizer's Viagra patent in China presents an early example of how Chinese business—in this case the domestic pharmaceutical industry—is adopting IPR laws as a business strategy. Here, domestic drug companies had begun to produce generic forms of Pfizer's erectile dysfunction drug Viagra before Pfizer was granted a patent on Viagra in China. Upon the grant of a patent to Pfizer, the domestic drug companies chose to not simply infringe Pfizer's patent rights, but rather decided to petition the government to invalidate the patent. Pfizer's patent was invalidated by the government's Patent Reexamination Board in a decision that attracted a great deal of criticism from the U.S. government and pharmaceutical industry. However, a similar Viagra patent in the U.K. had also been invalidated by the U.K. courts, and from that court's reasoning, it does not appear that China's decision was out-of-step with international IPR standards. Rather than criticize China's legal challenge of Pfizer's patent—as well as of other pharmaceutical patents—the international community should recognize this event as the beginning of a new phase in the promise of intellectual property rights protection in the People's Republic of China.

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175. U.S. Dept. of State, China: 2005 Investment Climate, <http://www.state.gov/e/eb/afd/2005/42000.htm> (last visited Nov. 29, 2005).