# FIGHTING POISON WITH POISON?: THE CHINESE EXPERIENCE WITH PHARMACEUTICAL PATENT LINKAGE

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## I INTRODUCTION

For years, the U.S. Trade Representatives and multinational pharmaceutical companies have pressed the Chinese government for stronger pharmaceutical IP protection within the drug regulatory framework. However, more pressing matters such as corruption scandals and tainted product scares plagued the State Food and Drug Administration (SFDA), leading to the execution of the State Food and Drug Administration commissioner in 2007.[1] The deputy commissioner who survived this purge was arrested under a different set of corruption charges in 2010.[2] During the worst of this tumultuous period, unscrupulous drug applicants submitted fake test results and plagiarized clinical data leaked by SFDA insiders.[3] Rigorous regulatory IP protection was extremely opaque against this chaotic institutional backdrop, and accounts of how it operates are few and incomplete.[4] Although the dust now has settled somewhat, the information we do have often resembles conflicting impressions passed between pharmaceutical and legal insiders.[5] As China is poised to become

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[*] Author's note.

[1] Simon Elegant, *A Chinese Regulator Sentenced to Die*, TIME.COM, (May 29, 2007), http://www.time.com/time/world/article/0,8599,1626042,00.html; Dali L. Yang, *Regulatory Learning and Its Discontents in China: Promise and Tragedy at the State Food and Drug Administration*, in PUSHING BACK GLOBALIZATION (John Gillespie & Randy Peerenboom, eds., London and New York: Routledge, 2009), *available at* http://www.daliyang.com/files/0_1_Yang_SFDA_regulatory_learning_and_its_discontents.pdf.

[2] Hepeng Jia, *Corruption at Chinese Drug Agency*, ROYAL SOCIETY OF CHEMISTRY, (Jul.-Sept. 2010), http://www.rsc.org/chemistryworld/China/Issues/2010/JulySeptember/CorruptionChineseDrugAgency.asp.

[3] Yang, *supra* note 3, at 6-8.

[4] Ron A. Bouchard, et al., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, 12 MINN. J.L. SCI. & TECH. 391 (2011) (mentioning the existence of linkage in China without discussion and comparing global linkage systems between U.S., Canada, Australia, Mexico, India, and South Korea); PHARMACEUTICAL, BIOTECHNOLOGY AND CHEMICAL INVENTIONS: WORLD PROTECTION AND EXPLOITATION, 589 (Duncan Bucknell ed., vol. 1, 2011) (reciting China's linkage regulations without discussion in a survey of global patent linkage law); Roy F. Waldron, *Linkage in International Pharmaceutical Patent Litigation*, 944 PLI/PAT 185 (Sept.-Oct. 2008) (summarizing international patent linkage rules without discussing China).

[5] *Compare* UNITED STATES TRADE REPRESENTATIVE, REPORT TO CONGRESS ON CHINA'S

the second largest pharmaceutical market in the world by 2013, innovators and generics companies lack a clearer picture of the pharmaceutical IP regulatory framework, especially the system of "patent linkage" that links (and conditions) the market approval of a drug to the status of potentially blocking patents.

This article examines the practical realities of China's patent-linkage system within the domestic institutional context. Contrary to what one may expect amid generics protectionism and public welfare concerns, Chinese patent linkage regulation is more pro-patentee on paper than its counterpart in the United States.[6] The problem of linkage enforcement invites a more mundane explanation—that of vague and overbroad regulations and a shaky agency overwhelmed by the strategic behavior of pharmaceutical companies, generics and patent owners alike.[7]

The government now indicates receptiveness to reprise regulatory IP protection under the national drive to pursue better healthcare and an innovation-driven pharmaceutical sector.[8] A notice and comment draft of "Regulation on Managing Intellectual Property Rights related to Medicines and Health" is circulating among experts within the Ministry of Health in China.[9] The China-US Workshop on Regulatory Data Protection for

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WTO COMPLIANCE, 89 (Executive Office of the President, Dec. 2010), *available at* http://www.ustr.gov/webfm_send/2460 ("At present, it appears that there is no effective administrative or civil recourse for patent owners to prevent the manufacture or sale of generic drugs that infringe their patents.") with Tony Chen, *Beijing High Court Upholds Viagra Patent in China*, IP PERSPECTIVES, 2008, at 30, *available at* http://www.jonesday.com/files/Publication/288b184e-c6ee-44b5-800f-30838f34da54/Presentation/PublicationAttachment/aa464b25-7839-4af9-be34-30d62faf4d56/Beijing_High_Court.pdf ("[A] Chinese patent is treated as valid until the invalidation decision has become final and nonappealable, and the State Food and Drug Administration of China will not grant marketing approval to generic drugs while a valid patent exists for the original product.").

[6] See *infra* Section ___.

[7] See *infra* Section ___.

[8] The Chinese side agrees to actively protect undisclosed pharmaceutical data required for marketing approval from unfair commercial use as well as to study the concrete measures for improving implementation thereof, so as to further encourage the innovation of new drugs. China and the United States agree to hold a seminar in 2011 in China to continue the discussion of this matter. UNITED STATES DEPARTMENT OF COMMERCE, 21ST U.S.-CHINA JOINT COMMISSION ON COMMERCE AND TRADE FACT SHEET (Dec. 15, 2010), *available at* http://www.commerce.gov/node/12467.

[9] Long Jiuzun(龙九尊), Yaopin Zhuce Yu Zhuanli Baohu Liandong Kunjing Poju （药品注册与专利保护联动困境破局）, Kexue Shibao (科学时报) [Science Times],（May 22, 2011, 20:12:31） http://news.sciencenet.cn/sbhtmlnews/2011/5/244637.html; 2011Nian Guojia Zhishi Chanquan Zhanlue Shishi Tuijin Jihua (2011 年国家只是传全战略实施推进计划)[The Promotion Plan for the Implementation of the National Intellectual Property Stradegy in 2011](April 21, 2011) http://www.nipso.cn/onews.asp?id=11315

Pharmaceuticals took place on June 20, 2011.[10] The official topic of the privately organized 2011 Sino-U.S. Pharmaceutical Industry Summit was "Intellectual Property Rights Protection & Pharmaceutical Industry Innovation and Development."[11] All signs indicate that China may update and improve its regulatory IP protection measures as we enter the 10-year anniversary of its patent-linkage regulations. This article aids that effort by examining China's trouble with patent-linkage beyond the broad stroke adversarial trade perspective that has come to dominate the discourse, with the hope of providing insights to policymakers during this window of change.

China's experience with patent linkage also holds many lessons for an increasing list of countries that have agreed to or are considering TRIPs-plus measures as part of a free trade agreement with the United States. For example, the South Korea-United States Free Trade Agreement requires the South Korean government to provide a system of patent linkage. It behooves Korean policymakers to examine the implementation and consequences of patent linkage in other countries.[12] For its next major trade effort, the United States proposed numerous intellectual property provisions into the Trans-Pacific Strategic Economic Partnership Agreement (TPP) which, if adopted, would introduce a robust patent linkage system into Australia, Brunei, Chile, Japan, Malaysia, New Zealand, Peru, Singapore and Vietnam.[13] Details of the Chinese experience can help potential TPP member countries identify concerns during trade negotiation and implement the actual patent linkage regime

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[10] Wo Zhuanweihui Weiyuan Yingyao Canjia Zhongmei Yaopin Shuju Baohu Zhidu Yantaohui (我专委会委员应邀参加中美药品数据保护制度研讨会)http://pharmaipr.oinsite.cn/_d271659518.htm (last visited Jan. 23 2012)

[11] 2011 SINO-U.S. PHARMACEUTICAL INDUSTRY SUMMIT, (Oct. 18-19, 2011), http://cupis.phirda.com/en/Default.aspx. (last visited Jan. 23, 2012)

[12] Sylvia Park, *Drug Approval-Patent Linkage System in the U.S. and Canada*, 38(3) J. KOR. PHARM. SCI. 207-215 (2008), *available at* http://210.101.116.28/W_kiss2/04902379_pv.pdf ("Article 18.9.5 of Korea-US Free Trade Agreement requires that Korea introduce the linkage system in drug marketing approval. However, Korea is unfamiliar with the linkage system.").

[13] Press Release, Office of the United States Trade Representative, Trans-Pacific Partnership Leaders Statement (Nov. 2011), *available at* http://www.ustr.gov/about-us/press-office/press-releases/2011/november/trans-pacific-partnership-leaders-statement (listing countries in currently in TPP negotiation); TRANS-PACIFIC PARTNERSHIP INTELLECTUAL PROPERTY RIGHTS CHAPTER Art. 9.5 (U.S. Proposed IP Provision, Sept. 2011), *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf (proposing a full-fledged patent linkage system); Doctors Without Borders, *How the Trans-Pacific Partnership Agreement Threatens Access to Medicines*, TPP ISSUE BRIEF, Sept. 2011, *available at* http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf (criticizing the TPP IP provisions, including patent linkage, for potentially limiting access to medicine).

after the negotiation. On this point, the SFDA's history with patent linkage offers a poignant demonstration of the institutional forces that shape regulatory practices during the globalization and localization process.

Part II summarizes the historical evolution of the patent linkage law in China as well as the history of its guardian, the SFDA. Part III examines each component of the patent linkage system in detail, including the new-drug/generics-drug divide, the drug-patent list, the patent-linked approval process, the drug patent dispute resolution, the post-registration cancellation process, and the patent challenge incentive system. The analysis references actual legal disputes and highlights any differences with the practice in the U.S. Part IV synthesizes these observations and clarifies specific scenarios when patent linkage fails to keep infringing drugs off the market. Part V reviews the current competitive potential of the Chinese pharmaceutical industry and considers the suitability of patent linkage in China. Should the Ministry of Health choose to update the patent linkage regulations, Part VI proposes five recommendations to promote patent linkage consistent with the capacities, aspirations and concerns of the pharmaceutical administrative agency. A key take-away lesson is that the patent linkage system strikes a delicate and complex balance such that minute regulatory shifts or institutional conditions engender unforeseen outcomes: a quest for more IP protection in China can destabilize the administrative system and leads to no protection.[14] This sensitivity to the local administration should offer a better chance of regulating generics entry and cementing patent linkage protection for all pharmaceutical innovators rather than an ever-escalating list of protective measures.

## II THE HISTORY OF PATENT-LINKAGE IN CHINA

Patent linkage "refers to a practice by some national regulatory authorities of denying approval of generic drugs that are 'linked' to an existing patent."[15] It originated in the United States under the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Act (hereinafter, HWA or "the Act").[16] At the time, "approximately 150 off-patent drugs had no generic competition" and the Act was designed with the eponymous goal of promoting drug price competition through the entry of generics drugs, by modifying the FDA

[14] Bouchard, et al., *supra* note 6, at 391-461.

[15] CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENT AND RELATED RIGHTS, 273 (Oxford University Press, 2011).

[16] Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § § 355, 360cc; 35 U.S.C. § § 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

registration requirement for generic drugs.[17] Under the Act, generics companies only need to show that their version of the drug is the equivalent of a brand name drug instead of duplicating the full gamut of expensive and time consuming clinical tests required to prove the safety and efficacy of a new drug.[18] In exchange for the use of this clinical data, brand companies are granted extensions of their patents for up to five years and the approval of generics is "linked" to the patent status of the brand drug.[19] Commentators generally praise the effect of the HW in the quarter century since, crediting it with the success of fostering a robust generics industry as a result of this balanced regulatory scheme, all while maintaining a R&D based innovative pharmaceutical sector.[20]

In an ironic twist, brand companies began exporting features of the Hatch-Waxman Act to protect their global market share against generics even though it was originally designed to promote pharmaceutical competition here in the United States. The pharmaceutical interest captured the United States Trade Representatives treaty negotiation agenda and inserted into free trade agreements several mechanisms of regulatory IP protection including, among others, patent linkage.[21] In 1993, Canada promulgated its own "Notice of Compliance" linkage regulation under NAFTA.[22] Mexico followed suit in 2003.[23] In 2005, the Australia-US

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[17] H.R. REP. NO. 98-857, pt. 2, at 27–33 (1984).

[18] Federal Food, Drug, and Cosmetic Act § 505(j); 21 U.S.C. § 355(j) (LexisNexis 2012).

[19] 35 U.S.C. § 156; 21 U.S.C. § 355(b), (c), (j); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 356-58 (2007) (discussing the Hatch-Waxman Act generally).

[20] Bouchard, et al., *supra* note 6, at 408; Aidan Hollis, *Closing the FDA's Orange Book*, REGULATION, Winter 2007, at 14–17, *available at* http://www.cato.org/pubs/regulation/regv24n4/v24n4-2.pdf; W. SCHACHT & J. THOMAS, CONG. RESEARCH SERV., IB 0105, THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS 1 (2004) ("Many experts agree that the Act has had a significant effect on the availability of generic substitutes for brand name drugs. Generics generally are rapidly available after patent expiration and at lower prices. Concurrently, given the increasing investment in research and development (R&D) and the gains in research intensity of the pharmaceutical industry, it appears that the 1984 Act has not deterred the search for and the development of new drugs.").

[21] SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (Cambridge Studies in International Relations, Cambridge University Press, 2003) (detailing the mechanisms through which multinational corporations dictated the U.S. policy that ultimately set the international IP agenda).

[22] Emir Aly Crowne & Cristina Mihalceanu, *Innovators and Generics: Proposals for Balancing Pharmaceutical Patent Protection and Public Access to Cheaper Medicines in Canada (or Don't NOC the Players, Hate the Regulations)*, 51(4) IDEA 693, 698 (2011).

[23] *See* Luis C. Schmidt, *Mexico moves to improve Pharmaceutical Product Registration Process*, ASIAN LAW IP REVIEW (Jan./Feb. 2004), *available at*

Free Trade Agreement became the first to export such regulatory IP protection outside of North America.[24] By the end of 2011, Chile, Singapore, Jordan, Morocco, Bahrain, Oman, Colombia, Peru, El Salvador, Honduras, Guatemala, Nicaragua, Costa Rica, Dominican Republic, Peru, and South Korea have entered into bilateral or regional agreements incorporating patent linkage.[25] The U.S. intellectual property amendment to the TPP, if ratified, will represent the next expansion to this list. Not surprisingly, major supply countries of generic drugs are not on this list yet. What is surprising, however, is that Chinese drug regulators have promulgated its own version of patent linkage as early as 2002 outside of any bilateral treaty obligation and despite its huge generics drug sector.[26] In other words, China is the first country to feature regulatory patent linkage outside of North America and has had linkage regulations on its books for a full decade.

A 1992 Memorandum of Understanding between the U.S. and China required China to protect the intellectual property rights embodied in pharmaceuticals which, up to that point, was not patentable.[27] Some commentators have traced the root of China's nascent patent linkage system to this Memorandum where "[t]he Chinese Government agrees to provide administrative protection to U.S. pharmaceutical … product inventions", although the Memorandum did not discuss pharmaceutical patent linkage as such.[28] On January 1, 1993, Chinese patent law was amended to permit

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http://www.olivares.com.mx/Knowledge/Articles/CopyrightArticles/MexicomovestoimprovePharmaceuticalProductRegistrationProcess (last visited June 13, 2011).

[24] AUSFTA, Art. 17.10.4; *see generally*, Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005) ("The recent Free Trade Agreement (FTA) with Australia requires linkage between drug approval and patent status for the first time, exporting a portion of Hatch-Waxman to Australia.").

[25] Chuan-feng Wu, *Raising the Right to Health Concerns Within the Framework of International Intellectual Property Law*, 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141, Table 1 (2010) (listing the pharmaceutical patent linkage provisions in all U.S. free trade agreements).

[26] YAHONG LI, IMITATION TO INNOVATION IN CHINA: THE ROLE OF PATENTS IN BIOTECHNOLOGY AND PHARMECEUTICAL INDUSTRIES (NEW HORIZONS IN INTELLECTUAL PROPERTY) (Edward Elgar Pub., Sept. 2010).

[27] Rongling Deng & Kenneth I. Kaitin, PhD, *The Regulation and Approval of New Drugs in China*, 37 DRUG INFORMATION J. 29-29 (2004), *available at* http://www.diahome.org/productfiles/8357/diaj_11235.pdf.

[28] Zhang Li (張鸝), Song Ruiling (宋瑞霖), Chen Changxion (陳昌雄), Shi Luwen (史錄文), 药品注册审批工作中专利相关问题探讨, Yaopin Zhuce Shenpi Gongzuo Zhong Zhuanli Xiangguan Wenti Tantao [Solving Patent Problem in the Registration and Approval of Drugs], 中国药房 Zhongguo Yaofang [China Pharmacy ] (2006) (Issue 09), http://wuxizazhi.cnki.net/Search/ZGYA200609000.html

the patenting of pharmaceuticals.[29] The Drug Administrative Protection Law was implemented at the same time and gave foreign companies 7.5 years of administrative market exclusivity for new drugs introduced into China.[30]

The law of pharmaceutical administration was revamped at the turn of the 21st century. The National People's Congress ratified the Drug Administration Law in 2001 and the State Council promulgated implementing regulations a year later.[31] China again updated its patent law to conform to the TRIPs agreement in 2002 and pharmaceutical IP protection gradually away from the 7.5 years administrative exclusivity to judicial protection that depends on the existence of patents with a concurrent patent linkage system under the 2002 Trial Measure for the Administration of Drug Registration.[32] Of all the national patent linkage systems, China's is the only one not obligated under bilateral treaties or FTAs, although its historical origins remain situated within the trade-related context of China's accession to the WTO and multinational pharmaceutical interest represented by the U.S. Trade Representative.[33]

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[29] Wei-Ning Yang & Andrew Y. Yen, *The Dragon Gets New IP Claws: The Latest Amendments to the Chinese Patent Law*, INTELL. PROP. & TECH. L.J., May 2009, at 18 (noting that the 1992 amendment added pharmaceuticals to patentable subject matter).

[30] Deng & Kaitin, *supra* note 28, at 30; Xia-Yun Gao, Comment, *An Introduction to Administrative Protection for Pharmaceuticals*, 9 DUKE J. COMP. & INT'L L. 259, 259 (1998) (providing an overview of administrative IP protection for pharmaceuticals).

[31] STATE FOOD AND DRUG ADMINISTRATION, DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA (effective December 1, 2001), http://former.sfda.gov.cn/cmsweb/webportal/W45649037/A48335975.html; STATE FOOD AND DRUG ADMINISTRATION, REGULATIONS FOR IMPLEMENTATION OF THE DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA (effective September 15, 2002), http://eng.sfda.gov.cn/WS03/CL0767/61640.html.

[32] The new regulation was administered by the State Drug Administration (SDA) until 2003, when the SDA took on food safety oversight and became the SFDA in 2003. Yang, *supra* note 3, at 1-2; Zhang Qinkui (张青奎), Yiyao Ji Shengwu Jishu Lingyu ZhishichanquanZhanlue Shiwu (医药剂生物技术领域知识产权战略实务), 188 (describing the administrative exclusivity as a by-product of China's transitional patent regime that is set to fade as drugs patented before 1993 gradually drops out of the period of exclusivity).

[33] WTO accession protocol did not require China to adopt patent linkage, but it did require China to grant a six year data exclusivity. WORLD TRADE ORGANIZATION, REPORT OF THE WORKING PARTY ON THE ACCESSION OF CHINA, WT/MIN(01)/3 (Nov. 10, 2001), *available at* http://www.mac.doc.gov/China/servicesschedule.pdf; *see also* Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 324-25 (2008) (reviewing the use of the Special and Priority 301 Watch List against countries include China for their failure to provide specialized pharmaceutical IP protection); TRADE COMPLIANCE CENTER, PEOPLE'S REPUBLIC OF CHINA INTELLECTUAL PROPERTY RIGHTS MEMORANDUM OF UNDERSTANDING (1992), http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_005362.asp.

The Trial Measure later became the official 2005 Measure for the Administration of Drug Registration, which coincided with the height of regulatory IP protection at the SFDA. The 2005 Measure explicitly allowed the SFDA to withhold or cancel a market registration pursuant to a finding of infringement by the courts or administrative bodies.[34] This period also witnessed the Viagra patent dispute—the most well-known instance of Chinese patent linkage in operation.[35] In 2004, a group of Chinese pharmaceutical companies tried to invalidate Pfizer's patent covering the use of sildenafil, the active ingredient of Viagra, for the treatment of male erectile dysfunction because the SFDA denied them market approval for a generics version of Viagra as a result of the blocking patent.[36]

Two years later, the pendulum swung the other way towards weaker linkage: An amendment removed the clause permitting the SFDA to withhold or cancel a registration.[37] This period also witnessed the rise of a Chinese Bolar exception, first in judicial decisions and latter in patent legislations.[38] Meanwhile, patent disputes between local pharmaceutical companies are on the rise. For example, Xianbei Welman Pharmaceutical Ltd. obtained 5 million RMB against an infringer of an antibiotic injection patent and Changchun Haiwai Pharmaceutical agreed to pay Chengdu Zhonghui one million RMB and ceased participation in drug procurement bids for infringing the patent of an herbal preparation.[39]

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[34] Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Measures for the Administration of Drug Registration] (promulgated by the St. Food & Drug Admin., effective May. 01, 2005) ) (China) Article 12. available at: http://www.sda.gov.cn/WS01/CL0053/24510.html (专利权人可以依据管理专利工作的部门的最终裁决或者人民法院认定构成侵权的生效判决，向国家食品药品监督管理局申请注销侵权人的药品批准文号。国家食品药品监督管理局据此注销侵权人的药品批准证明文件. [patentees can petition to the State Food and Drug Administration to cancel a infringer's registration for the infringing drugs, with the final judgment from the relating Patent regulation agencies or an effective judgment from the court.）

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[36] 国产“伟哥”仍未有准生证 推广步履艰难 Guochan "Weige" Reng Weiyou Zhunshengzheng Tuiguang Bulü Jiannan, 信息时报, Xinxi Shibao[Information Times], (Aug. 18, 2005) http://finance.sina.com.cn/b/20040728/1026907233.shtml

[37] *Compare*, PROVISIONS FOR DRUG REGISTRATION (SFDA Order No. 28) Art. 18, *available at* http://former.sfda.gov.cn/cmsweb/webportal/W45649039/A64028429.html ("Where a patent dispute occurs in the process of drug registration, it shall be settled in accordance with relevant laws and regulations on patent."), *with* Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Measures for the Administration of Drug Registration] (promulgated by the St. Food & Drug Admin., effective May. 01, 2005) ) (China) Art. 12, *available at*: http://www.sda.gov.cn/WS01/CL0053/24510.html.

[38] See infra note ___ and accompanying text.

[39] 10-Q Quarterly Report, NeoStem, Inc., Legal Proceedings (Sept. 2011), *available at*

## III THE CHINESE PATENT LINKAGE SYSTEM

China's nascent patent linkage regulations mirror many of the Hatch-Waxman features, leading some observers to conclude that China is now among the list of countries with patent linkages.[40] But a closer examination reveals the work of a distorting mirror. As it turns out, small differences in the key components alter the fundamental workings of the patent linkage system.

### *A. The New-Generic Drug Divide*

Thus the first issue during the design of patent linkage is the line-drawing between a novel drug and a generic drug. The current Hatch-Waxman act does not provide any regulatory process for managing potential patent infringement issues of an innovative drug that creates its own clinical data. Patent linkage does not come into play for new drug applications even when the drug implicates the patent rights of another. The burden of the patent-linkage compliance is reserved for drug applications that make use of previously generated clinical data of another drug via what is known as the Abbreviated New Drug Application or ANDA.[41] Thus generic drugs in the U.S. are drugs that relied on the clinical trial of another through the ANDA process, even though the Hatch-Waxman itself does not use the term "generic drug."

Chinese drug registration regulations ostensibly observe the difference between a new drug and a generic drug. A new drug application is defined as any drug that has not been sold in China, which includes any new indication, new formulation, new delivery route or bio-

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http://google.brand.edgar-online.com/EFX_dll/EDGARpro.dll?FetchFilingHtmlSection1?SectionID=8152051-836551-840763&SessionID=0ZJXFC9JmyT5p77#V234855_424B3_HTM_TOC (discussing the Welman/Erye dispute); News, LexField Law Offices, On March 8, 2011, a patent infringement dispute in the Chinese medicine field was settled by mediation where LexField represented the patentee in front of the Beijing Higher People's Court by turning the defeat into victory and achieving substantial success in the second instance (Mar. 8, 2011), *available at* http://www.lexfieldlaw.com/templates/T_second_en/index.aspx?NodeID=181&page=ContentPage&contentid=1308 (discussing the Zhonghui/Haiwai dispute).

[40] HO, *supra* note 16, at 278 (listing Canada, Australia, China, Jordan, Mexico, UAE, and Singapore as countries with patent linkage).

[41] 21 U.S.C. § 355(b)(2) (requiring patent certification only for drugs where the clinical trials relied upon "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted").

similar product.[42] Applicants of a new drug must supply clinical data to demonstrate drug safety, efficacy and quality.[43] A generic application is an application for any chemical entity drug that is based on a previously approved drug.[44] Applicants of a generic drug must demonstrate that the generic drug candidate is biologically equivalent to a previously approved drug.[45] The similarity stops at the patent linkage system. Unlike its U.S. predecessor, the Chinese patent linkage system applies to all drug applications, without the limitations to generics products or small chemical molecules under the Hatch-Waxman Act.[46] This contrasts with the regulatory arrangements in the United States that limit patent linkage to the approval of generics products, where small chemical entities and biological products are further divided into two disparate linkage regimes.[47]

This unusual breadth converts patent linkage from a ministerial task to a discretionary task and hampers the SFDA's ability to implement patent linkage in an orderly way.[48] The SFDA and applicants have an easier time anticipating patent conflicts for generics drugs because each generics application references a previously approved drug, where the patents associated with the approved drug meaningfully narrows the universe of patents on which drug approval may turn. In contrast, a new drug application implicates the entire category of chemical and medical patents. By 2005, the SFDA admits relying on what seems an *ad hoc* mix of patentee monitoring, applicant self-reporting, and its own judgment call for patent linkage enforcement.[49]

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[42] PROVISIONS FOR DRUG REGISTRATION (SFDA Order No. 28), Art. 12, *available at* http://former.sfda.gov.cn/cmsweb/webportal/W45649039/A64028429.html;
[43] *Id.* at Art. 31.
[44] *Id.* at Art. 74.
[45] Foley & Lardner, Generic Drug Approval Process in China, *available at* http://www.foley.com/files/tbl_s31Publications/FileUpload137/8364/RizziLin_DrugApproval.pdf ("To the extent possible, bioequivalence testing is an important aspect of the SFDA approval process for generic drug applications.").
[46] PROVISIONS FOR DRUG REGISTRATION (SFDA Order No. 28), Arts. 12, 18 & 19, *available at* http://former.sfda.gov.cn/cmsweb/webportal/W45649039/A64028429.html (articulating linkage mechanisms without distinguishing between generics or noval drugs).
[47] 21 U.S.C. § 355(b)(2) (requiring certification only for drugs undergoing the ANDA path) and 42 U.S.C. § 262(k) (requiring a special generics approval path for biosimilars).
[48] Karen Halverson, *China's WTO Accession: Economic, Legal and Political Implications*, 27 B.C. INT'L & COMP. L. REV. 319, 352-53 (2004) (noting a characteristic of Chinese law that "[T]entative, broadly worded rules create a broad sphere of authority and promote discretionary decision-making on the part of interpretive bodies.").
[49] US-CHINA JOINT COMMISSION ON COMMERCE AND TRADE MEDICAL DEVICE AND PHARMACEUTICAL SUBGROUP PHARMACEUTICAL TASK FORCE MEETING (Beijing, China, Aug. 30, 2005), *available at* http://ita.doc.gov/td/health/jcctpharma05_1.pdf.

### *B. Patent Disclosure*

The patent-linkage system requires a registry that explicitly identifies the patents covering an approved pharmaceutical product.[50] This registration system allows drug regulatory agencies to quickly evaluate the IP status of a generic drug application, i.e. whether the pending drug candidate implicates the patents of another. In the Hatch-Waxman Act, the registry is officially known as the list of "Approved Drug Products with Therapeutic Equivalence and Evaluations" and colloquially known as the Orange Book.[51] The Act does not require the patentee to list every patent that may cover the drug, and generic companies review the Orange Book to determine whether their generic version of the drug will infringe any listed patents. Patentees may withhold additional relevant patents that it is ready to assert against the generics company from the Orange Book listing. However, these unlisted patents cannot prevent the FDA from approving the generic drug application.

Article 18 of the 2007 Measure provides the basis of the Chinese drug-patent registry. The first paragraph of Article 18 states that "the applicant shall submit documents explaining the patent status in China owned by itself ..." and "for the explanation … from the applicant, the [SFDA] shall display them on its website."[52] Since 2008, the SFDA began hosting its drug patent data disclosure website, which currently contains 1250 entries of drug-patent pairs as of June 1, 2011. The website is searchable by various data fields including the applicant name, the active ingredient, the Brand name, and so forth, recalling the FDA portal for the Orange Book.[53] Unlike the Orange Book, the list permits a generics applicant to identify its own patents. Table 1 is a sample entry for the fixed-dose combination drug Caduet for the treatment of high cholesterol and high blood pressure. It shows a number of fields responding to fairly detailed information. At first glance, the SFDA drug patent result appears to provide the type of patent-linkage information found in the Orange Book.

TABLE I

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[50] The Hatch-Waxman Act, 21 U.S.C. 355(b)(1) (2000); 21 C.F.R. §314.53.
[51] U.S. FOOD AND DRUG ADMINISTRATION, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (providing an electronic version of the Orange Book).
[52] PROVISIONS FOR DRUG REGISTRATION (SFDA Order No. 28), Art. 18, *available at* http://former.sfda.gov.cn/cmsweb/webportal/W45649039/A64028429.html [hereinafter Article 18].
[53] STATE FOOD AND DRUG ADMINISTRATION, P.R. CHINA, http://eng.sfda.gov.cn/WS03/CL0755/.

| | |
|---|---|
| 受理号 (App. No.) | JYHB0901140 国 |
| 药品名称 (Prod. Name) | Amlodipine Besylate and Atorvastatin Calcium Tablets氨氯地平阿托伐他汀钙片 |
| 申请人 (Applicant) | Pfizer Inc. |
| Pat. Type专利 | Composition Patent化合物专利 |
| Pat. No. 专利名称 | |
| Mail No. 邮编 | |
| Pat. Exp.专利到期日 | 2001-5-23 |
| Foreign Pat.外国专利 | US5747498 |
| For. Patentee 外国专利人 | 1998-5-5 |
| Contact 申请人联系地址 | Schoenmattstrasse 2,4153 Reinach, Switzerland |
| Patentee 专利人 | Pfizer Inc. (America)美国辉瑞有限公司 |

However, a closer examination of Table I reveals a number of inconsistencies ranging from the obvious to the egregious:

(1) Table I does not identify a specific Chinese patent anywhere;
(2) The Patent Number field is left blank;
(3) The date of "1998-5-5" is clearly an irrelevant and incorrect entry for the Foreign Patentee field;
(4) Although Table I lists Pfizer as the drug applicant and the patentee, the applicant contact address ("Schoenmattstrasse 2,4153 Reinach, Switzerland") belongs to Roche Pharma (Schweiz) AG, the Swiss pharmaceutical giant;
(5) The Patent Expiration Date field lists 2001-5-23, but Pfizer did not even submit the New Drug Application for Caduet to the United States FDA until October 12, 2005, well after the supposed expiration date; and
(6) Even more surprisingly, the patent US 5,747,498 does not correspond to the drug Caduet at all. Instead, it corresponds to Tarceva, a cancer treatment drug marketed by Roche.[54]

[54] The Tarceva Orange Book entry lists U.S. Pat. No. 5747498. U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021743&Product_No=001&table1=OB_Rx and http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021743&Product_No=001&table1=OB_Rx (). The Caduet Orange Book listing does not contain U.S. Pat. No. 5747498. *Id.* at

As this review shows, the drug-patent entry appears to be a random mishmash of information drawn from two completely unrelated drugs and, as a result, is completely incorrect. A further search shows that, unlike the Orange Book where a single drug entry contains all associated patent information, the SFDA patent disclosure website returns a deluge of discrete drug-patent entries of uncertain accuracy. For example, a search for Caduet based on its product name in TABLE I (氨氯地平阿托伐他汀钙片 or Amlodipine Besylate and Atorvastatin Calcium Tablets) returns 27 different entries, all of which contain varying degrees of inconsistencies. Only three of these 27 entries contain a Chinese patent number that is relevant for patent-linkage reference in China.[55] Likewise, a search for Tarceva based on its product name (盐酸厄洛替尼片 or Erlotinib) returns 30 different entries, of which four identify a Chinese patent relevant for patent-linkage. TABLE II provides an example of a "more correct" entry for Caduet.

TABLE II

| | |
|---|---|
| App. No. 受理号 | JYHF0800039 辽 |
| Prod. Name 药品名称 | Amlodipine Besylate and Atorvastatin Calcium Tablets氨氯地平阿托伐他汀钙片 |
| Applicant 申请人 | Pfizer Inc. |
| Pat. Type专利 | Composition Patent 化合物专利 |
| Pat. No. 专利名称 | ZL96195564.3 |
| Mail No. 邮编 | |
| Pat. Exp.专利到期日 | 07/10/02 |
| Foreign Pat.外国专利 | US 6,455,574 B1 |
| For. Patentee 外国专利人 | Pfizer Inc |
| Contact 申请人联系地址 | 235 East 42nd Street, New York, NY 10017, U.S.A. |
| Patentee 专利人 | (Warner Lambert) 沃尼尔.朗伯公司 |

http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021540&TABLE1=OB_Rx and http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021540&Product_No=001&table1=OB_Rx.

[55] On file with Author. The three entries appear to correspond to three drug applications that differ by the concentration of the active ingredient.

This entry contains more accurate information. However, crucial mistakes remain. The Chinese patent ZL96195564.3 should expire 20 years from its filing date on July 8, 2016, not October 7, 2002 as the expiration date is listed here.[56]

In summary, the current SFDA drug-patent registration list fails to provide the needed notice to generics or the protection to innovators because it has no legal force and contains many errors. A Chinese attorney concludes that users of the drug-patent registry should "verify a hit, suspect a miss."[57] In other words, any patent turned up by a search of the drug-patent registry should be separately verified. Likewise, generic applicants should view with suspicion a search that fails to uncover any patent, since relevant patents may not have been recorded correctly.

### *C. Statement of Non-Infringement*

Under the Hatch-Waxman Act, a generic drug application (an Abbreviated New Drug Application or ANDA) must certify that the sale of the drug will not violate those patents listed under the reference drug in the Orange Book and identify at least one basis for the certification, such that no patent exist, the patent is or will be expired, not infringed, or invalid.[58] The generics applicant must provide a basis of non-infringement to every patent listed in the Orange Book.[59] A certification that the patent does not cover the generic drug or that the patent is invalid (as opposed to reasons of non-violation due to patent expiry) will alert the patentee and possibly trigger patent litigation that tests the scope and validity of the patent in court.[60] In short, a generics applicant's certification puts the patentee on notice and sets in motion the patent litigation that will resolve the rights of the generics company *vis-a-vis* the patentee. This arrangement is possible because the generics company must reference the patented drug in order to take advantage of a faster and cheaper approval process, and because the reference to the Orange Book automatically implicates a list of patents *identified by the patentee*, who has an incentive to list .[61]

When the listed patent covers a method of use corresponding to a

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[56] Chinese Patent No. ZL96195564 (issued July 10, 2002)

[57] Tong Hongyan (佟红岩)， Kaiqi Zhuanli Xinxi Zhimen (开启专利信息之门), [open the door for patent information],（Feb. 26, 2009） www.yyjjb.com.cn/html/2009-02/26/content_85223.htm

[58] 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

[59] 21 U.S.C. § 355(b)(2)(A).

[60] 21 U.S.C. § 355(b)(3); 21 U.S.C. § 355(c)(3)(c).

[61] 21 U.S.C. § 355(b)(1).

medical condition, the generics company may register the same chemical for a different medical condition that is not covered by the patent without running afoul the patent. In this circumstance, the registrant can make a "section 8" statement declaring its intention not to seek approval for an indication covered by the condition, in lieu of the non-infringement certification.[62] A Section 8 statement is not communicated to the patentee, and the FDA will not withhold drug registration based on a Section 8 statement.

In China, the same Article 18 that mandated the drug-patent list requires drug applicants to guarantee non-infringement, but its scope appears much broader than what is required under the Hatch-Waxman Act: the Chinese non-infringement guarantee is required of all drug applications, without the limitations to generics products or small chemical molecules under the Hatch-Waxman Act. The relevant part of Article 18 states:

> If others hold a patent in China, the applicant shall submit a letter of guarantee stating that the pharmaceutical will not infringe the patent rights of others. … For the … declaration from the applicant, the [SFDA] shall display them on its website.[63]

The letter of non-infringement guarantee appears to parallel the ANDA certifications or Section 8 statement. Moreover, the website publication of these non-infringement guarantees should serve a similar notice function even though Article 18 does not require the SFDA or the drug applicants to notify the patentee of these guarantees.

Interestingly, Article 18 does not contain any specific language limiting linkage to generics applicants or to a specific set of patents, in contrast to the regulatory arrangements in the United States, Canada or Mexico that limits patent linkage to only the approval of generics and only those patents listed in the patent registry.[64] According to details further specified in the SFDA instruction to new drug applicants seeking manufacturing approval:

> The applicant must submit the patent search information relating to the pharmaceutical, in order to prove that the application does not involve the existing patent rights of another. For searches that identified another possessing patents in China, [applicant] shall discuss the relevant situation in detail and explain reasons of non-infringement. Regardless of whether [the applicant] possess any Chinese patent, [the applicant] shall provide the relevant search information, guarantee that the patent rights of another are not

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62 21 U.S.C. § 355(j)(2)(A)(viii).
63 Article 18, *supra* note 53.
64

> infringed, and promise to bear all responsibilities with respect to possible infringement.[65]

Thus, Chinese patent linkage regulation imposes on all drug applicants—new or generics—a duty to conduct patent search, disclose relevant patents, and guarantee non-infringement.

But despite its overall similarity in structure to the U.S. linkage and its even broader scope, this legal structure does not work well in practice. For example, the United States Council for International Business complained to the U.S. Trade Representatives that the non-infringement declarations are not published to this day, contrary to SFDA's own provisions.[66] In their absence, the patentee cannot defend its own rights, either by engaging the applicant-infringer in litigation or informing the SFDA of potential infringements by the applicant.[67]

Beneath the procedural criticisms are two deeper shortcomings. First, the non-infringement guarantee lacks sufficient detail such that even a publication/notice system will not improve notice in actuality. A blanket guarantee of non-infringement and a statement to assume the risk of potential liabilities is all that is required of the applicants.[68] It need not identify any patents or state the basis of non-infringement. Therefore, even if the declarations are published, the patentees are still without knowledge that their patents may be in the process of infringement by a drug applicant. The Chinese patent-linkage system depends on patentee vigilance. The SFDA describes its internal process as follows:

> First, in initially accepting an application, SFDA requires subsequent registrants to first check the patent status of the product and provide information/report that indeed its product would not infringe on a patent, and to acknowledge it would be liable for damages if indeed there is infringement.

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[65] Xinyao Huozhe Yiyou Guojia Biaozhun de Huaxue Yaopin Shengchan pizhun (新药或者已有国家标准的化学药品生产批准) [The Regulation of Approval of New Drugs or the Drugs Already Met the National Standards] (Feb. 20, 2006) http://www.sda.gov.cn/WS01/CL0372/24064.html

[66] Letter from Peter M. Robinson, President and CEO & Clarence T. Kwan, China Committee Chair, The United States Council for International Business, to Gloria Blue, Office of the U.S. Trade Representative (Sept. 30, 2010), *available at* http://www.uscib.org/docs/P_USCIB_Submission_to_USTR_China_Compliance_with_WTO_Commitments_09_30_10.pdf.

[67] LI, *supra* note 27, at 145; THE AMERICAN CHAMBER OF COMMERCE IN SHANGHAI, 2003 WHITE PAPER: AMERICAN BUSINESS IN CHINA (2003), *available at* http://www.amcham-shanghai.org/AmChamPortal/MCMS/Presentation/Publication/WhitePaper/ChairmanMessage.aspx?Year=2003.

[68]

> Second, if SFDA is contacted by a patent holder claiming infringement, then SFDA would contact the subsequent registration applicant in writing, sending a copy to the patent holder. This document would presumably be admissible in court. It would ask the applicant to review the situation again, and state whether it intends the SFDA to continue the registration process. If the answer is affirmative, the applicant must submit a second letter claiming non–infringement and again acknowledging liability for damages if there is infringement. Otherwise the applicant should withdraw its application. [69]

Second, the disarray of the drug-patent registry provides the drug applicant and the SFDA with plausible deniability that they lack knowledge of potential blocking patents. Although the non-infringement guarantee requirement broadly covers any drug applications, the reality is that applicants of new or generic drugs can almost always guarantee non-infringement without fear of being contradicted by the available information. The regulation does not demand any minimum quality of patent search or freedom-to-operate opinions. Therefore, the drug-patent registry remains the only guidance for citing potential blocking patents. But because the drug-linkage data is incomplete and because the non-infringement guarantee need not identify patents with specificity, the registration and certification processes do not connect patentees with generics companies during the drug registration stage. Thus in practice, the non-infringement guarantee appears little more than an administrative CYA for the SFDA.

### *D. Patent-Linked Approval*

The FDA provokes the parties to litigate by delaying the approval of a drug that infringes the patents in the Orange Book. It is for this patent-linked drug approval process that the overall "patent linkage system" came to be referred. The FDA can withhold generics registration pending the outcome of patent litigation for up to 30 months or until the litigation resolves in favor of the generics company, whichever occurs first.[70]

Article 19 of the 2007 Measure provides a patent linked approval process that is ostensibly more favorable to the patentee than its U.S. counterpart:

> As to a drug for which others have obtained patent protection in China, one may apply for registration two years prior to the expiration of the patent. ... SFDA shall review the application ... and, after expiration of the patent, issue

[69] U.S.-China Joint Commission, *supra* note 46, at 4.
[70] 21 U.S.C. § 355(j)(5)(b)(iii).

the [Registration].[71]

In theory, this unequivocal rule should prevent a drug application from entering the approval pipeline unless the patent is set to expire within two years, and appears broader than its U.S. counterpart that permits the FDA to process the application any time before the expiry of a blocking patent (as long as the FDA does not grant actual approval).[72] In China as in the U.S., the regulation promises administrative approval after patent expiry.[73]

SFDA did in fact withhold generics approval based on blocking patents, as exemplified in the situation of the often reported Viagra patent dispute when the SFDA did not approve the generic sildenafil (the active ingredient of Viagra) applications filed by a group of Chinese generics companies due to Pfizer's blocking patent. In response, the Chinese generics manufacturers formed the "Viagra Alliance" and jointly challenged the validity of Pfizer's Viagra patent in SIPO.[74] Tarceva, a lung cancer treatment that Shanghai Roche Pharmaceutical Ltd launched in 2007, provides another example of effective patent blockade.[75] There are no generic Tarceva approved for sale in China, despite the technical capacity to duplicate and a strong price incentive. The genuine Tarceva costs 19,800 RMB per package of 30 pills.[76] Tarceva manufactured by the Indian generics company Cipla were reportedly smuggled into China for 5,500 RMB.[77] Domestic counterfeit Tarceva sold for a mere one-tenth of the genuine product, according to the testimony of Dr. Jiayi Ding, a Chinese American returnee scientist who received a 10 year sentence for manufacturing and selling Tarceva from a garage, in a case which SIPO came to refer to as one of the top ten counterfeit drug busts.[78] Finally, even absent patent linkage, the threat of infringement litigation remains a

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[71] Article 18, *supra* note 53.

[72] 21 USC 355(j)(5)(B)(iv)(II)(dd) (defining "tentative approval" where the FDA determines that the drug meets approval requirements other than patent conflicts).

[73] Article 18, *supra* note 53; 21 U.S.C. § 355(b)(2)(A)(ii)-(iii).

[74]

[75] Pan Letian, ed., *Cancer Drug Hits Market*, CHINA VIEW (Mar. 19, 2007), http://news.xinhuanet.com/english/2007-03/19/content_5866771.htm.

[76] Ren Peng (任鹏)，Mianfei Juanzeng Beihou de Tianjia Jiuming Yao (免费捐赠背后的天价救命药) Qilu Wanbao (齐鲁晚报) (Sep. 19,2011)]]http://epaper.qlwb.com.cn/images/2011-09/19/B02/qb0219.pdf.

[77] *Id.*

[78]Guojia Shipin Yaopin Jianguanju Gongbu Shida Jiayao Dianxing Anjian (国家食品药品监管局公布十大假药典型案件) （Jan. 06, 2011） http://www.sipo.gov.cn/mtjj/2011/201101/t20110124_569538.html; Liubo (刘波)，Zhongfa (钟法)， Hangzhou Zuida Yiqi Zhishou Jiayao An Zuo Kaiting （杭州最大一起制售假药案昨开庭） (Oct. 23, 2010) Jinri Zaobao (今日早报) available at : http://jrzb.zjol.com.cn/html/2010-10/23/content_579253.htm?div=-1

deterrent. This should lay to rest USTR's doomsday claim that "there is no effective administrative or civil recourse ... to prevent the manufacture or sale of generic drugs that infringe their patents."[79]

On the other hand, the SFDA does not always succeed with its gate-keeping function. The SFDA official, describing the process in 2005, highlights the "porousness" of patent linkage review. First, SFDA lists all drug registration applications by chemical name on its website and, according to one SFDA official, it is up to the patent owners to check the SFDA website frequently and notify the SFDA if it observes possible infringement.[80] The SFDA grew uncomfortable as an arbiter of patents conflicts and formally declared such function beyond its authority in 2006.[81] In response to questions submitted by the provincial SFDA office in Szechuan, the central SFDA issued an administrative opinion confirming its retracement:

> Drug Control Law, Drug Control Law Implementing Regulations, and the Measure for the Administration of Drug Registration provides that the condition of drug registration is safety, efficacy and quality control, which does not require performing patent examination with respect to the registering drug.[82]

During a meeting of the US-China Joint Commission on Commerce and Trade, SFDA representatives expressed the sentiment that "Chinese law does not authorize SFDA to act as DE and IPR policeman."[83] At a later JCCT meeting, Deputy Director Jianhua Ding of the Department of Drug Registration at the SFDA declared: "SFDA is not responsible for IPR. IPR should be discussed with the China IPR Bureau."[84]

### *E. Patent Dispute Resolution*

Although the system of patent linkage is sometimes described as a blanket bar against the approval of potentially infringing pharmaceuticals, strictly speaking it is a mandatory litigation trigger, instead of an

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[79] UNITED STATES TRADE REPRESENTATIVE, REPORT TO CONGRESS ON CHINA'S WTO COMPLIANCE, 89 (Executive Office of the President, Dec. 2010), *available at* http://www.ustr.gov/webfm_send/2460.

[80] U.S.-China Joint Commission, *supra* note 46.

[81] *Infra*

[82] Guanyu Ganlu Jutangtai Youguan Zhishi Chanquan Wenti de Yijian (关于甘露聚糖肽有关知识产权问题的意见) [The 2006 Opinion On Mannatide Related to Intellectual Property Questions] (Issued June 13, 2006), available at: http://www.sda.gov.cn/WS01/CL0495/10563.html

[83] U.S.-China Joint Commission, *supra* note 46.

[84] *Id.*

independent protection. When generics companies and patent owners conflict over patent coverage, FDA will prohibit generics registration only after the patent owner decides to file an infringement lawsuit.[85] This prohibition dissolves if the patent owner loses the litigation or if the litigation lasts beyond 30 months.[86] In short, patent linkage converts the act of drug registration into a technical patent infringement.[87] Such "technical" infringement should not be confused with litigation triggered by traditionally infringing acts performed leading up to an application registration. Generics companies often have to make or import drugs that violate the patents of another in order to conduct experiments that generate the required bio-equivalence data. In order to promote generics entrance, the Hatch-Waxman Act exempts these preparatory activities from the definition of patent infringement under what is known as the Bolar exemption.[88] The United States Supreme Court have interpreted this provision broadly to immunize infringing preclinical and clinical activities relating to any compounds for which regulatory approval could be sought.[89]

Article 18 of the 2007 Measure similarly describes possible patent infringement litigation in the context of drug registration:

> If disputes over patent rights arise in the registration process, relevant laws and regulations shall be followed for a solution.[90]

A plain reading of this regulation implies that, if the patent owner and generics registrant disagree in the course of the registration process, the patent laws ("the relevant law") should apply and it is up to the courts and the patent office to sort out infringement issues. Unlike the Hatch-Waxman Act, the SFDA regulation does not create a new cause of patent infringement based on drug registration.

Previously, Chinese courts reached inconsistent decisions as to whether

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[85] 21 U.S.C. § 355(c)(3)(C).
[86] 21 U.S.C. § 355(j)(5)(b)(iii).
[87] 35 U.S.C. §271(e)(2).
[88] 35 U.S.C. §271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.").
[89] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005). The WTO also endorsed a Bolar-like exemption in Canada when the United States and EU filed a complaint in the WTO against Canada alleging its Bolar exemption of allowing generics manufacturers to make and sell the patented compounds for regulatory review violated TRIPs. PANEL REPORT, CANADA--PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS, WT/SD114/R (Mar. 17, 2000).
[90] Article 18, *supra* note 53.

the unauthorized making and using of patented products during the course of preparing for a drug registration constituted patent infringement. In 2000, the Chongqing Intermediate People's Court imposed damages against generic company for the unauthorized use of patented technology in connection with drug approval in *Glaxo v. Southwestern Pharmaceuticals*.[91] In 2005, the Jilin Intermediate People's Court ordered a generic defendant to stop its drug registration process after finding that the unauthorized use of patented traditional medicine formulation in the course of registration is intended for infringing production in *Chengdu Kanghong Pharmaceuticals v. Liyuan Pharmaceuticals*.[92] Other courts were less sympathetic to the patentee, as illustrated by the *Sankyo v. Beijing Wansheng* case in 2006 and the *Eli Lilly v. Ganli* case in 2007.[93] In both instances the generic defendants made and used patentee's drugs within the scope of the patent but the patentees were denied relief.[94] Although the Chinese Patent Law did not contain a Bolar exemption at that time, the courts relied on two other statutory provisions: the experimental exception and the requirement that infringing acts be performed for a commercial or business purpose.[95]

When Chinese patent law was amended in 2009, a statutory Bolar exemption was added to exempt from infringement liability acts performed in the course of drug registration:

> None of the following shall be deemed an infringement of the patent right:
>
> …
>
> (5) For the purpose of providing information needed for administrative examination and approval, any person makes, uses, imports a patented medicine ....[96]

As a result, although Art. 18 of the 2007 Measure requires registration related dispute be handled through relevant laws and regulations, such disputes do not exist according to the "relevant law."[97] The statutory

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[91] LI, *supra* note 27, at 147.

[92] Jiling, Chengdu Kanghong Zhiyao Youxian Gongsi Su Jilin Sheng Liyuan Yaoye Gufen Youxian Gongsi (吉玲，成都抗弘制药有限公司诉吉林省力源药业股份有限公司) [Jiling, Chengdu Kanghong Pharmaceuticals Ltd. v. Jilin Province Liyuan Pharmaceuticals stock corp.], (Jilin Province Changchun Interm. People's Ct. Jan. 10, 2008) (China).available at: http://ipr.court.gov.cn/jl/zlq/200801/t20080110_123029.html

[93] *See* LI, *supra* note 27, at 147-48 (discussing the Sankyo v. Wansheng and Eli Lilly v. Ganli in the context of Chinese Bolar exception).

[94] *Id.*

[95] CHINESE PATENT LAW, Arts 11, 69(4) (2002).

[96] CHINESE PATENT LAW, Art. 69(5) (2009).

[97] PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), SPECIAL

Bolar exemption became the exception that swallowed the rule of patent linkage since 2009.

The SFDA adopted an expansive view of Article 69(5) that removes all patent related considerations from the ambit of SFDA review, ostensibly because the exemption in Article 69(5) is national law promulgated by People's Congress and trumps the SFDA patent linkage regulation.[98] This explanation is not completely satisfying: Article 69(5) speaks of infringement liability, while SFDA regulation uses patent clearance as a condition of approval—these two procedures can co-exist without overt conflict. Even some Chinese commentators have noted their compatibility.[99] Nonetheless the SFDA has withdrawn from substantive patent linkage review today and patent owners lack a cause of action against pre-market conducts.

Two dispute resolution mechanisms have the potential of resolving pharmaceutical IP disputes before market approval. First, drug registrants can challenge the validity of a blocking patent through traditional patent law means—a re-examination request through the State Intellectual Property Office. The famous Viagra litigation arose in this context when the SFDA refused to approve generics drugs due to Pfizer's blocking sildenafil

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301 SUBMISSION 2010 37-38 (2010), *available at* http://keionline.org/sites/default/files/PhRMA_USTR-2010-0003-0245.1.pdf .

> However the patent laws essentially require there to be sales in the marketplace before an infringement suit can be filed. In addition, the "Bolar Exemption" provision in the current draft Amendment of the Patent Law exempts without condition any production of patented products from infringement as long as it is "for the purpose of submitting information necessary for an administrative approval". As a result, PhRMA member companies have not been able to resolve patent disputes prior to marketing approval.

*Id.*

[98] Lijun (李军), Zhuanli Lianjie Zhidu Xu Wanshan (专利链接制度需完善), [Patent Linkage System Needs Profection], Zhongguo Yiyao Bao （中国医药报）[China Pharmaceutical News], (Mar. 12, 2011), available at: http://www.yybnet.com/site1/zgyyb/html/2011-03/12/content_45688.htm (questioning the continued viability of patent linkage under the drug registration regulations after the Third Amendment).

[99] Shan Weiguang (单伟光), Shen Ximing (沈锡明), Sun Guojun (孙国君), Zhuanlifa Disanci Xiugai Zhi "Bolar Liwai" Jiqi Dui Yiyao Zhizaoye de Fangda Xiaoying (《专利法》第三次修改之"Bolar 例外"及其对医药制造业的放大效应) [The "Bolar" Exception in the Third Amendment of the Patent Laws and It's Aggregated Effects in the Pharmaceutical Industry], 2010 Nian Zhongguo Yaoxue Dahui Ji Dishijie Zhongguo Yaoshizhou Lunwenji (2010 年中国药学大会暨第十届中国药师周论文集), (2010) available at: http://cpfd.cnki.com.cn/Article/CPFDTOTAL-YYWS201011002979.htm

patent.[100] Another example of this procedure is the blocking patent covering the anti-diabetic drug Avandia marketed by GlaxoSmithKline. When Chinese generics companies initiated a re-examination, GlaxoSmithKline gave up its patent.[101] These invalidity battles are not limited to multinational-domestic company disputes. For example, Welman pharmaceutical company owns a patent on an injectable antibiotics combination.[102] Eleven pharmaceutical companies brought an invalidity proceeding in 2002 and prevailed before SIPO and Beijing Intermediate People's Court but Beijing High People's court sided with the patent owner and upheld the patent's validity.[103] The Supreme People's Court eventually weighed in and sided with the challengers in December 23, 2011, 9 years after the initial invalidation proceeding.[104] Generics companies are fearful of patent litigation with or without linkage, and one can expect pharmaceutical companies to continue the game of chess before the Patent Re-examination Board at SIPO.

As the Welman patent example shows, invalidity proceedings in SIPO may not always resolve drug patent disputes early. Owners of weak patents may delay case resolution to hold up generics applicants. Aggressive generics companies may also marketing the drug first and file dilatory invalidity challenges only after the patent owner brings a patent infringement suit. Pfizer's Viagra patent dispute is an exception in this regard—the drug and the patent are exceedingly well-known such that generics companies cannot feign ignorance of the patent when they seek market approval, and the SFDA cannot grant market approval in good or bad faith. Only then were the generics companies forced to invalidate

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[100] J. Benjamin Bai, Peter J. Wang & Helen Cheng, *What Multinational Companies Need to Know about Patent Invalidation and Patent Litigation in China*, 5 NW. J. TECH. & INTELL. PROP. 449, *2 (2007), *available at* http://www.law.northwestern.edu/journals/njtip/v5/n3/4/; Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in China in the Twenty-First Century*, 55 AM. U. L. REV. 901, 985 (2006); Jeffrey A. Andrews, *Pfizer's Viagra Patent and the Promise of Patent Protection in China*, 28 LOY. L.A. INT'L & COMP. L. REV. 1 (2006) (detailing the Viagra dispute).

[101] Bai, Wang & Cheng, *supra* note 101, at *3; Richard McGregor, *Glaxo Fight to Defend Diabetes Patent in China Is Abandoned*, FIN. TIMES, Aug. 19, 2004, at 21; Andrews, *supra* note 101, at [redacted].

[102] Chinese Patent No. ZL97108942.6 (issued Dec. 06, 2000) ; Xiao He (肖贺), Liu Zhengwu （刘正午）, Paishu Zhuanli Jieshu Qinian Zhitong (哌舒专利结束"七年之痛"), Yiyao Jingji Bao (医药经济报), (Apr. 23, 2010), available at: http://www.yyjjb.com.cn/html/2010-04/23/content_112506.htm

[103] Id.

[104] Hou Lihong ( 侯利红)， Shuanghe Yaoye Shengsu Paishu Zhuanli Jiufen An (双鹤药业胜诉哌舒专利纠纷案), (Dec. 28, 2011), available at: http://www.ipr.gov.cn/alxdarticle/alxd/alxdzl/alxdzlgnal/201112/1273520_1.html

Pfizer's patent before market approval.

Ironically, the fraud and omission used by some generics applicants to evade regulatory scrutiny may offer an alternative basis of litigation that confers the same benefit to the patent owners as patent linkage. Under the Administrative Permission Law, registration applications containing fraudulent data or deliberate omissions are subject to penalty and denial.[105] Also under the 2007 Measure, any company that obtained registration through fraud will have all subsequent drug application refused for five years.[106] It is unclear whether SFDA's anti-fraud regulations creates a private right of action for regulatory infraction, but some have suggested the possibility of blocking infringing registration by initiating a civil fraud action in People's courts.[107]

Fraud and knowledge of the patent may be evidenced through several paths. First, correct registry data creates notice of the patent information against which knowledge of patents may be imputed on the generics applicants. Second, patent owners can often learn of a generics registration or clinical trial application in the SFDA approval pipeline through the grapevine, at which point a cease and desist letter will vest the generics applicants with knowledge of the patent and trigger their disclosure obligation or risk a fraud charge. Third, knowledge can be inferred from conduct. For example, Shuanghe pharmaceutical asked SIPO to invalidate a blocking patent in 2002. Meanwhile, its registration application was moving through the SFDA and gain approval in 2003 even though the patent was still in force at the time.[108] Clearly Shuanghe had knowledge of the patent based on its invalidation claim as of 2002—either Shuanghe withheld that information from the SFDA or the SFDA failed to act on that information. In the end Welman's patent was invalidated recently after ten years of litigation, and the infringing registration was "no harm, no foul" in retrospect. Nonetheless the circumstance of Shuanghe's approval does not bode well for the integrity of the linkage system.

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[105] ADMINISTRATIVE PERMISSION LAW OF THE PEOPLE'S REPUBLIC OF CHINA (ORDER OF THE PRESIDENT NO. 7), Arts. 78-79 (2004), *available at* http://english.gov.cn/laws/2005-09/07/content_29926.htm.

[106] PROVISIONS FOR DRUG REGISTRATION (SFDA Order No. 28), Art. 167 (2007), *available at* http://former.sfda.gov.cn/cmsweb/webportal/W45649039/A64028429.html.

[107] Conversation with GlaxoSmithKline Counsel, in PLACE (DATE).

[108] See Fei Na(斐娜), Guanyu Yaopin Zhuce Zhong de Zhuanli Wenti de Anli Fenxi 9 关于药品注册中的专利问题的案例分析), Masters Thesis, 兰州大学, Lanzhou University, 15-16 (April 7, 2010) (discussing timeline of the Shuanghe/Welman disputes and Shuanghe's implied knowledge of the Welman patent).

### *F. Patent Challenge Incentive*

Launching a patent challenge against the innovators is an expensive proposition. A 2011 AIPLA estimate pegs the average cost of high stake patent litigation at $6 million, which is comparable to older estimates that ANDA litigation costs $5 million.[109] Moreover, subsequent generics companies can often enter the marketplace by freeriding a successful challenge without funding their own litigation, thereby undermining economic incentive of launching a patent challenge. To mitigate the free rider problem and to reward generics challenges, the Hatch-Waxman Act grants the first generics applicant who successfully challenged a patent a 180-days exclusivity period, during which time no second generics company may market the same drug.[110] The institution of the 180-day exclusivity has been praised for noticeably promoting generics entry,[111] although it recently came under attack for becoming a tool that brand drug companies buy from generics companies through "reverse payment settlements" to block competitor entry.[112]

Chinese linkage regulations do not provide patent challenge incentive beyond the reward of ordinary market entry. But generics challenges are alive and well, due to a different legal and economic environment. First, the cost of patent challenge is much lower—it is estimated that patent litigation costs around $60,000 to $120,000 on average in China, which is a small fraction of the $5 million U.S. price tag.[113] Therefore the financial

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[109] THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION (AIPLA), REPORT OF THE ECONOMIC SURVEY (2011), http://www.patentinsurance.com/iprisk/aipla-survey/; Matthew J. Higgins & Stuart J.H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326(5951) SCI. 370 (Oct. 16, 2009).

[110] 21 USC 355(j)(5)(B)(iv) (laying out the 180 day exclusivity reward for the first generics applicant successfully prevailed over an Orange Book patent).

[111] Ernst R. Berndt, et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26(3) HEALTH AFFAIRS 790 (2007), *available at* http://content.healthaffairs.org/content/26/3/790.full ("Changes in FDA administrative law awarding 180-day exclusivity offer one possible reason for the greater frequency of recent patent challenges and awarding of exclusivity.").

[112] *See e.g.*, D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 118-120, 132-33 (2011) (reviewing criticisms of the 180 exclusivity and proposing an amendment to turn the exclusivity "rolling."); Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489 (2007); A. Engelberg, *Special Provisions for Pharmaceuticals: Have They Outlived Their Usefulness*, 39 J. L. & TECH. 389, 423-25 (1998) (calling for the end of the 180 day exclusivity).

[113] Ian Harvey, *Intellectual Property: china in the Global Economy – Myth and Reality*, INTERNATIONAL IP STRATEGISTS ASSOCIATION BRIEFING NOTE (Sept. 2011),

expense of a patent challenge is likely to be much lower for a generics challenger in China and quicker to recover for the first mover, which in turn lessens the impact of free-riders.

The size of the potential market may have also encouraged Chinese generics companies to band together and challenge the patents covering particularly profitable drugs, thereby avoiding the free-rider problem all together. The Viagra patent validity challenge was the joint effort of twelve companies.[114] Eleven companies jointly challenged Welman's antibiotics patent.[115] Four companies jointly challenged GlaxoSmithKline's rosiglitazone patent, an ingredient for its Avandia drug.[116] These patent-challenge alliances lower the cost of invalidity challenges borne by each company and reduce the risk that one generics company will free ride off the patent challenge success of another generics company, obviating the need for special incentives.

### *G. Post-Registration Cancellation*

In the U.S., patent linkage does not have a retroactive effect—a successful registration survives all subsequent patent disputes even if the generics company is later adjudged an infringer.[117] In other words, U.S. patent linkage does not provide a mechanism for post-registration cancellation. Generics companies occasionally adopt the strategy of "at risk launch" and put an approved product on the market before a trial court resolved potential patent infringement claims.[118] Examples of at-risk-launches in the U.S. include Apotex launching the generic version of

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https://workspace.imperial.ac.uk/business-school/Public/research/I_Egroup/IPRC/IP_in_china_Ian_harvey.pdf.

[114] *See* Andrews, *supra* note 101, at 18 (citing Audra Ang, *Chinese Companies Hoping to Copy Viagra*, BOSTON GLOBE, Dec. 6, 2002, at A40, *available at* 2002 WLNR 2594224).

[115] _____, *supra* note ___, at ____.

[116] Jia Hepeng, *Pharmaceutical Giant Gives Up Medicine Patent*, CHINA BUSINESS WEEKLY, reprinted at CHINA DAILY (Aug. 26, 2004), http://www.chinadaily.com.cn/english/doc/2004-08/26/content_369176.htm ("In early 2004, four domestic drugmakers including Shanghai-based Sunway Pharmaceutical Co Ltd, Chongqing-based Taiji Group and Zhejiang Wanma Pharmaceutical Co Ltd, and Chengdu Hengri Pharmaceutical Co Ltd… filed an application in SIPO to invalidate GSK's … patent"); *compare with* Andrews, *supra* note 101, at 18 (naming three companies not including Chengdu Hengri Pharmaceuticals Co. Ltd.).

[117] Sanofi-Aventis, et al. v. Food and Drug Administration, et al., 725 F. Supp. 2d 92, 95 (D.D.C. 2010) (permitting the FDA to approve a generics drug on the day a district court renders a decision of non-infringement notwithstanding a later reversal of the decision on appeal).

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Sanofi-Aventis' Plavix after the FTC rejected their patent dispute settlement or Ivax and Teva launching AstraZeneca's Pulmicort Respules after the expiration of the 30-months stay.[119]

In contrast, the SFDA and Chinese courts have struggled with post-registration cancellations over the years. Regulatory reforms and judicial decisions now appear to move towards the U.S. approach.[120] Initially, the 2002 Trial Measure for the Administration of Drug Registration adopted a non-committal position. That trial measure left it up to the parties, the courts and patent administrations to resolve post-registration patent disputes.[121] Three years later the SFDA took a more strident stance towards infringing drugs. Under the 2005 Measure, a patent owner may ask the SFDA to revoke the marketing approval of an infringer based on the final decision of a patent administrative agency or a judgment of infringement from the People's court.[122] In fact, Welman Pharmaceutical petitioned the SFDA to cancel the registration of potentially infringing antibiotic injection drugs.[123] But critics faulted this approach for exceeding SFDA's health and safety mandate.[124]

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[119] *Update 1- U.S. Appeals Court Upholds $442 Million Plavix Award*, REUTERS (Oct. 18, 2011), http://www.reuters.com/article/2011/10/18/sanofi-apotex-patent-idUSN1E79H1NL20111018; Sanofi-Synthelabo et al. v. Apotex, 550 F.3d 1075 (Fed. Cir. 2008) (affirming the finding that Apotex infringed Sanofi's patent for launching its generics of Plavix at risk); Jeffrey Bouley, *AstraZeneca and Teva settle generic Pulmicort squabble*, DRUG DISCOVERY NEWS (Dec. 8, 2008), http://www.drugdiscoverynews.com/index.php?newsarticle=2601; *see generally*, RBC CAPITAL MARKETS, PHARMACEUTICALS ANALYZING LITIGATION SUCCESS RATES, (Jan. 15, 2010), at 7, available at http://amlawdaily.typepad.com/pharmareport.pdf (charting 28 at-risk launches between 2003 and 2009).

[120] Yaopin Zhuanli Lianjie Zhidu Jixu Jianli (药品专利链接制度亟须建立), (Oct. 31, 2011), available at: http://www.cu-market.com.cn/hgjj/2011-10-31/14412243.html

[121] Yaopin Zhuce Guanli Banfa (药品注册管理办法(试行)) [Measures for the Administration of Drug Registration (for trial implementation)] (promulgated by the St. Food & Drug Admin., Oct. 30, 2002, effective Dec. 01, 2002) ) (China). According to the this trial implementation of the regulation, patent disputes after the application and registration of the drugs at issue, should be resolved by the parties at issue on their own, or through the judicial efforts and relevant patents administrating agencies.

[122] Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Measures for the Administration of Drug Registration] (promulgated by the St. Food & Drug Admin., effective May. 01, 2005) ) (China) Article 12; A patentee can request the State Food and Drug Administration to cancel the infringer's drug registration according to a valid judgment from the patents administration agencies or a court order.
(专利权人可以依据管理专利工作的部门的最终裁决或者人民法院认定构成侵权的生效判决，向国家食品药品监督管理局申请注销侵权人的药品批准文号。国家食品药品监督管理局据此注销侵权人的药品批准证明文件。) http://former.sfda.gov.cn/cmsweb/webportal/W53384/A64002493.html; Structure-Function Analysis, Bouchard 459 ("Chinese regulators have jurisdiction to revoke approval of generic products based on patents granted to brand firms.").

[123] Huang Haijun (黄海昀), Weierman Zhuanli An Zhuizong: Baiyunshan BUqinquan Susong An Yanhou (威尔曼专利案追踪：白云山不侵权诉讼案延后), (Aug. 18, 2005), http://finance.sina.com.cn/roll/20050818/0935270907.shtml

[124] Zhang Li (張麗), Song Ruiling (宋瑞霖), Chen Changxion (陳昌雄), Shi Luwen (史

The SFDA retreated from this position in the updated 2007 Measure, deleting the paragraph authorizing post-registration cancellation. [125] Recently, the head of the Drug Registration department confirmed that the SFDA will not revoke a registration due to patent infringement concerns, confirming the end of post-registration cancellation.[126] Consistent with this position, Chinese judges have refused to issue an order revoking drug registration. In Xiangbei Welman Pharmaceutical Ltd. v. Suzhou Erye Pharmaceutical Ltd., another one of the Welman antibiotic injection patent disputes, the patent owner sought the remedy of an order revoking the defendant's market approval.[127] The Hunan High People's court affirmed infringement, granted a 5 million RMB award, and issued an injunction prohibiting ongoing manufacture and sales. But it denied the cancellation request after noting that the remedy had no legal basis.[128] Thus Chinese patent linkage appears to have stabilized on the side of no revocation, consistent with the rule in the United States.

## IV PATENT-LINKAGE IN-OPERATION: GETTING SFDA APPROVAL OVER A PATENT

The detailed comparison of the patent linkage regime in the U.S. and China provides a basis for examining five scenarios by which a potentially

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錄文), 药品注册审批工作中专利相关问题探讨, Yaopin Zhuce Shenpi Gongzuo Zhong Zhuanli Xiangguan Wenti Tantao [Solving Patent Problem in the Registration and Approval of Drugs], 中国药房 Zhongguo Yaofang [China Pharmacy ] (2006) (Issue 09), http://wuxizazhi.cnki.net/Search/ZGYA200609000.html

[125] *Compare* Article 18, *supra* note 53 ("Where a patent dispute occurs in the process of drug registration, it shall be settled in accordance with relevant laws and regulations on patent.") *with* Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Measures for the Administration of Drug Registration] (promulgated by the St. Food & Drug Admin., effective May. 01, 2005) ) (China) Art. 12 http://www.sda.gov.cn/WS01/CL0053/24510.html.

[126] Yaopin Zhuanli Lianjie Zhidu Jixu Jianli (药品专利链接制度亟须建立), (Oct. 31, 2011), available at: http://www.cu-market.com.cn/hgjj/2011-10-31/14412243.html (批准文号也不因专利影响是否批准。"这意味着, 一项侵犯他人专利的药品有可能获得sfda的批准文号, 而且也不会因为侵权遭sfda注销。[meaning that an infringing drug might obtain registration from the State Food and Drug Administration, and the registration will not be cancelled because of the infringing conduct.] )

[127] Xiangbei Weierman Zhiyao Youxian Gongsi Su Suzhou Eryan Zhiyao Youxian Gongsi, Hunan Weichu Yiyao Youxian Gongsi Qinfan Faming Zhuanli Jiufen Yi An (原告湘北威尔曼制药有限公司诉被告苏州二叶制药有限公司、湖南唯楚医药有限公司侵犯发明专利权纠纷一案) [Xiangbei Welman Pharmaceutical Co., Ltd. v. Suzhou Erye Pharmaceutical Co., Ltd, and Hunan Weichu Pharmaceutical Co., Ltd], (Hunan Sup. People's Court May. 19, 2011) available at: http://www.iamiplawyer.com/fangchan/anlijiexi/zhuanli/1160.html.

[128] Id.

infringing generics can receive SFDA approval during unexpired patent terms during much of China's patent linkage experience: (1) as a new drug application; (2) as a generics application without an explicit blocking patent (3) as an application before patent grant (4) as a fraudulent application; and (5) as a non-infringing application according to the SFDA. After 2009, the SFDA essentially abdicated from any linkage based review based on a broad reading of the statutory Bolar exemption under the newly amended patent law.[129]

### *A. New Drug Applications*

A generics company can register a new drug application and avoid referencing a previously approved drug that is protected under patents. Without this reference, the SFDA may not realize that this "new" drug is in fact a generic version covered by the patents of an existing drug.[130]

A registrant in the United States can also avoid patent linkage under the Hatch-Waxman Act since the act provides even less (read: none) patent-linkage for new drug applications than the SFDA regulation. However, the cost of conducting clinical trials to support a new drug application in the FDA far outweighs the cost of patent litigation and generic company would be better off challenging a suspect patent in litigation under an ANDA application rather than pursuing a NDA application.[131] Moreover, if the patent is unassailable, the generic drug will invite an immediate infringement litigation and judicial injunction even if with FDA approval. Thus, a rational company will not submit a generics drug for new drug registration.

In contrast, a generics company has ample incentives to pursue a new drug application in China under a different economic calculus. The SFDA regulation defines "new drug" as one that has not been sold in China under

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[129] *See supra* sec. IIIE.

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[131] Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The price of innovation: new estimates of drug development costs*, 22(2) J. HEALTH ECON. 151–85 (2003) (estimating that each newly approved drug costs $800 million to $1 billion, with approximately 70% of that being the cost of clinical trials); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 10-11 (2009) (discussing the high cost of clinical trial). See also Christopher Paul Adams & Van Vu Brantner, *Estimating the Cost of New Drug Development: Is It Really 802 Million Dollars?*, 25(2) HEALTH AFF. (MILLWOOD) 420-428 (2006); Christopher Paul Adams & Van Vu Brantner, *Spending On New Drug Development*, 19(2) HEALTH & ECON. 130-141 (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1002/hec.1454/abstract.

the same formulation, delivery route or indications.[132] A drug approved under the new drug path is entitled to greater pricing power under a procurement scheme set by the government.[133] A generics company can easily qualify for a higher profit margin by changing the formulation of a known approved drug to satisfy the definition of a new drug.[134] Although a new drug application requires new clinical data, the cost of clinical trial can be as low as a third of its cost here in the United States.[135] Industry insiders also observe "indirect reliance" whereby Chinese generic companies "take the publicly-available FDA summaries" of the innovator's product "and use the data therein to support their own copied products in their SFDA submissions."[136]

The economic shift from favoring generics in the FDA to favoring new drugs in the SFDA means that, all else being equal, more Chinese drug candidates will enter the new drugs pipeline that enjoys a lenient review because it is similar or identical to a foreign drug that is protected under a foreign patent not recognized by the SFDA. The fact that the Chinese patent linkage system also covers new drug applications is an understandable response to the problem of generics drugs being filed as new. But the broader coverage comes with a price—a new drug application needs not reference a previously approved drug that is linked to Chinese patents, and infringement is inherently more difficult to detect or establish absent such reference. Broad protection comes with an administrative price.

### *B. Incomplete Listing*

Even if an infringing generics application references and relies on the data of a patented drug, the SFDA may grant registration when the patent

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133 http://www.haiweb.org/medicineprices/surveys/200609CNS/survey_report.pdf ("Pharmaceutical companies report the cost of their off-patent or originator drugs to the State Development and Reform Committee; these are priced separately, beyond the allowed threshold for generic drugs.").

134 *See supra* sec. IV.

135 According to the Business Week May 28, 2007, the savings on each study patient in China can be as high as two-third of its cost in the U.S. In 2007, the cost of an artificial liver trial was $15,000 per patient in China vs. $50,000 in the U.S. *The Rush to Test Drugs in China: Despite Ethical Concerns, Big Pharm is Recruiting More Patients for Clinical Trials*, BUSINESSWEEK.COM (May 28, 2007), http://www.businessweek.com/magazine/content/07_22/b4036076.htm.

136 U.S. INTERNATIONAL TRADE COMMISSION, CHINA: INTELLECTUAL PROPERTY INFRINGEMENT, INDIGENOUS INNOVATION POLICIES, AND FRAMEWORKS FOR MEASURING THE EFFECTS ON THE U.S. ECONOMY (Nov. 2010), at p. 4-7 box 4-1, *available at* http://www.usitc.gov/publications/332/pub4199.pdf [hereinafter ITC Study].

owner failed to list a patent or listed its patent under incomplete or misidentified drug-patent entries as we have seen with Caduet. In theory, the generics application may infringe other patents not identified in the drug-patent list, but regulators ignore these unlisted patents because they do not have the expertise or authority to mine patent databases and conduct freedom-to-operate analysis on their own, unless the patent is as famous as the one covering Viagra. Thus in practice, SFDA regulators invoke patent linkage only when a generics application falls within the scope of a drug-patent previously identified to them.

The Chinese drug-patent registry lacks the accuracy and comprehensiveness of an authoritative drug-patent pair database, unlike the Orange Book that unequivocally identifies the patents in play during regulatory approval. The database may simply fail to list the drug-patent entry and sever the linkage. For example, Welman pharmaceutical company received patent ZL97108942.6 on a Piperacillin Sodium and Sulbactam Sodium antibiotic injection formulation in 1998.[137] This patent was the subject of an ownership dispute,[138] an 80 million RMB licensing deal that went south,[139] an invalidation proceeding brought by 11 pharmaceutical companies,[140] a CIETEC arbitration decision,[141] and infringement actions that went all the way up to the Supreme People's Court.[142] Even now, at least six generic products are on the market with SFDA approval.[143] Yet despite all of this, a search for piperacillin sodium and sulbactam sodium or ZL97108942.6 in the SFDA drug-patent database returns no result.

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[137] ZL97108942.6 Fayuan Dui Suzhou Erye Zhiyao de Caiding (法院对苏州二叶制药的裁定), （Aug. 26, 2009） available at: http://blog.tianya.cn/blogger/post_show.asp?idWriter=0&Key=0&BlogID=2272023&PostID=18705136

[138] Xiangbei Weierman Zhiyao Youxian Gongsi yu Guojia Zhishi Chanquanju Deng Zhuanli Xingzheng Jiufen Yi'an, (Aug. 14, 2009), Available at: http://www.law-lib.com/cpws/cpws_view.asp?id=200401351840

140. Weierman Zhuanli An Jiang Shouchang Jiufen Sheji 12 Jia Yiyaoqi (威尔曼专利案将收场 纠纷涉及 12 家医药企) [Welman Patent Case comes to the end, dispute involves 12 pharmaceutical companies], （Aug. 3, 2010） , available at : http://www.36683.com/news/42706.shtml

[140] Id.

[141] "Paishu" Zhuanli An Weierman Gongsi Huopei 470wan ("哌舒"专利案 威尔曼公司获赔 470 万), (Aug. 31, 2010), available at: http://news.9939.com/xwdc/2010/0831/1281833.shtml

[142] 6 Fayuan Dui Suzhou Erye Zhiyao de Caiding (法院对苏州二叶只要的裁定), （Aug. 26, 2009） available at: http://blog.tianya.cn/blogger/post_show.asp?idWriter=0&Key=0&BlogID=2272023&PostID=18705136

[143] "Paishu" Zhuanli An Weierman Gongsi Huopei 470wan ("哌舒"专利案 威尔曼公司获赔 470 万), (Aug. 31, 2010), available at : http://news.9939.com/xwdc/2010/0831/1281833.shtml

Defective entries also sever linkage and permit the registration of infringing drugs. Recall that the drug-patent entries for Caduet or Tarceva listed incorrect patent expiration dates, which creates an appearance that the patents are no longer enforceable.[144] Therefore, a law-abiding generic applicant searching the SFDA website may find drug-patent data showing expired patents, which in turn allows that applicant to state in good faith that no patents are infringed by its generic product. Likewise, unscrupulous copyists can hide within gaps in the drug-patent data, making deliberately false non-infringement representations without fear of being called out by the patentee.

### *C. Chronological Gap*

In the third scenario, the SFDA may have approved a generics drug before the corresponding patent covering the drug has been issued. This direct situation is non-existent in the United States: Companies file patents for promising compounds long before the start of clinical trials, and patent protection is well established by the time the FDA approves the new drug. In fact, the company may terminate a project if patent protection is not available. However, a variation does exist where the pharmaceutical company lists a newly granted improvement patent to block generic entry after the generics company lodged an application.[145] In order to promote generics entry, the Hatch Waxman Act was amended to prevent the use of a later listed patent to retroactively bar a previously filed application.[146]

In China, a generics drug may receive market approval while the corresponding Chinese patent application moves through the patent office, sowing the seed for future infringement disputes when the patent finally issues. The docetaxel dispute between Sanofi-Aventis and Hengrui Medicine exemplifies this timing issue. In 1989, Rhone-Poulenc Santi (now part of Sanofi-Aventis) received a U.S. patent covering docetaxel, an anti-tumor drug derived from taxol, and the FDA approved docetaxel for

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[144] *See supra* sec. IIIB.

[145] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, v (FTC July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (discussing the abuses of using a later listed patent to obtain multiple 30-months stay against the approval of generics products); *see* Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 176-194 (2005) (discussing the problem of multiple 30-months stay and the 2003 amendment to stop the abuse).

[146] *Id.*

prostate cancer treatment in 2004.[147] However, Sanofi-Aventis did not receive the formulation patents in China until 2006.[148] Before SIPO granted that patent, a Chinese company Hengrui Medicine applied for and obtained a registration for its formulation of the drug in 2003.[149] When the Chinese patent finally issued, it generated several rounds of litigation between Hengrui and Sanofi-Aventis.[150]

This timing gap between Sanofi applying for the patent in 1993 and finally receiving the patent in 2006 may be caused by historical conditions as China's early patent system struggle with foreign filings and pharmaceutical composition patents.[151] But the same timing issue can arise even between two Chinese firms whenever patents arrive late and drug approval arrives early, as illustrated through a three-year long patent dispute between Chengdu Zhonghui Pharmaceutical Co. Ltd. and Changchun Haiwai Pharmaceutical Group Ltd. Chengdu Zhonghui applied for an invention patent for its arthritis drug *Tongfong Ding Pang* (痛风定片) in 2004 and received the patent in 2006.[152] Before the patent was granted, however, Changchun Haiwai received marketing approval on May 17, 2005. Recently the parties settled after three years of litigation: Changchun Haiwai agreed to pay Chengdu Zhonghui 1 million RMB and ceased participation in drug procurement bids.[153] Notwithstanding its ultimate victory, the IP Manager of Chengdu Zhonghui urged the SFDA to strengthen patent linkage in order to avoid unnecessary infringement litigation.[154] But what was the SFDA to do when the corresponding Chinese patents did not exist at the time?

Under a similar timeline and circumstance, the FDA in the United States would have approved drugs that are covered by a later issued patent. Perhaps the SFDA can apply a later issued patent retroactively and revoke

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[147] U.S. Patent No. 4,814,470 (filed July 14, 1987) (issued Mar. 21, 1989); U.S. FOOD AND DRUG ADMINISTRATION, FDA APPROVES NEW INDICATION FOR TAXOTERE-- PROSTATE CANCER, FDA.GOV (May 19, 2004), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108301.htm.

[148] Chinese Patent No. ZL02147245.9 (issued Dec. 27, 2006).

[149] Hu Fang (胡芳), Duoxitasai Zhuanli Beipan Wuxiao (多西他赛专利被判无效), Zhongguo Yiyao bao (中国医药报) [China Pharmaceutical News], (June 9, 2011), available at: http://www.yybnet.com/site1/zgyyb/html/2011-06/09/content_49714.htm

[150] Id.

[151] See Chinese Patent No. ZL02147245.9 (issued Dec. 27, 2006). .

[152] Chinese Patent No. 200410040542.8 (issued Nov. 29, 2006).

[153] Long Jiuzun(龙九尊), Yaopin Zhuce Yu Zhuanli Baohu Liandong Kunjing Poju （药品注册与专利保护联动困境破局）（May 22, 2011, 20:12:31） http://news.sciencenet.cn/sbhtmlnews/2011/5/244637.html

[154] Id. ("有些侵权药品在注册审批时通过了，我们还得通过诉讼来解决，这对我们来说比较费事" [ "[When] some infringing drugs pass through the registration approval, we have to resolve the problem through litigation—which is more troublesome for us.])

its previously granted market approval, but doing so would open a whole can of worms and would certainly be above and beyond the call for patent linkage. In no countries can a drug agency revoke an approval based on a later granted patent. In this regard, the SFDA and linkage regulations may have born unmerited criticism.

### *D. Outright Fraud*

Some infringing registration can be attributed to persistent fraud and corruption within the pharmaceutical sector. In a study targeting the transparency and integrity of drug regulators, the World Health Organization noted that "[t]he pharmaceutical sector is particularly vulnerable to corruption, which manifests itself in various forms, including bribery, fraud, favouritism, collusion and embezzlement at different levels of the medicines chain."[155] So pervasive is the corruption problem that twenty-six countries have voluntarily joined the WHO that launched the Good Governance in Medicine problem designed to "strengthening and prevent corruption by promoting good governance in the pharmaceutical sector."[156] During the late 80s, the division of the FDA responsible for the approval of generics drugs was embroiled in corruption. Department of Justice investigation revealed generics drug companies using money and gifts to influence FDA administrators, submitted fraudulent ANDA data, providing brand company drug as samples of their generic product.[157] The fraud perpetrated during the first ten years of SFDA's experience with linkage law, then, follows a universal tradition of extra-legal influences against drug regulators.

As the purveyor of market approvals, the SFDA stands between pharmaceutical companies and their immediate profit and market share. Xiaoyu Zheng, the executed former commissioner of SFDA mentioned earlier, was convicted of corruption for taking bribe from at least eight

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[155] WORLD HEALTH ORGANIZATION & AUSTRALIAN GOVERNMENT, MEASURING TRANSPARENCY IN MEDICINES REGISTRATION, SELECTION, AND PROCUREMENT iii (WTO 2006), *available at* http://www.who.int/medicines/areas/policy/goodgovernance/Transparency4CountryStudy.pdf.

[156] THE WORLD HEALTH ORGANIZATION, GOALS AND SPECIFIC OBJECTIVES, http://www.who.int/medicines/areas/policy/goodgovernance/goal_objectives/en/index.html.

[157] Joseph P. Reid, 75 Notre Dame L. Rev. 309, 321-322 (Oct. 1999) (recounting the generics scandal three years after the passage of the Hatch-Waxman Act); *The Generic Drug Scandal*, N.Y. TIMES (Oct. 2, 1989), http://www.nytimes.com/1989/10/02/opinion/the-generic-drug-scandal.html.

pharmaceutical companies and executed in 2007.[158] More recently in 2010, Deputy Commissioner Zhang Jingli who survived the earlier purge was dismissed, arrested and tried for corruption charges.[159] During trial, he was accused of anonymously attacking the current Commissioner of the SFDA with corruption charges online, in an attempt to disgrace his boss and snatch the leadership position.[160] Prof. Dali Yang examined the failure of the SFDA as a case study of the Chinese administrative organ and noted extensive fraud aided by a lack of oversight at the SFDA.[161]

> Fraud was also not unusual, however, and there was little double-checking of data submitted. The SFDA had simply withdrawn from the actual certification process. Some pharmaceutical companies would systematically fake data needed for GMP certification by filling up the required forms for over half a year with fake data.[162]

Although he addressed the process of Good Manufacturing Practice (GMP) standard approval, such brazen fraud reflects a culture of pervasive corruption. The GMP incidents also share with linkage issues the tension between grandiose industrial policy and administrative implementation, as both were promulgated to promote a R&D and quality pharmaceutical industry away from low-level imitations. But compared with the enforcement linkage regulations, the GMP upgrade is squarely within its health and safety mandate and need not heed politically sensitive complications of IP policy, foreign trade and vocal foreign corporation. If the SFDA lacked the institutional wherewithal to perform the ideologically simple GMP inspections with impartiality, query whether we truly expect the SFDA to enforce a robust linkage regime.

Neither was the SFDA always a tacit accessory—bribed SFDA bureaucrats actively undermined the integrity of the drug approval process by selling confidential drug registration data:

> Most remarkably, some of the personnel working at the drug registration bureau sold copies of application documents supplied by legitimate

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[158] *Former Head of China's Drug Watchdog Executed*, CHINA VIEW, (Jul. 10, 2007), http://news.xinhuanet.com/english/2007-07/10/content_6353536.htm; Jean-Francois Tremblay, *Chinese Drug Official Gets Death Sentence*, CHEMICAL & ENGINEERING NEWS, (May 30, 2007), http://pubs.acs.org/cen/news/85/i23/8523news2.html.

[159] *Former Deputy Director of China's Drug Watchdog Sacked*, CHINA DAILY (Jan. 7, 2011), http://www.chinadaily.com.cn/usa/business/2011-01/07/content_11867400.htm; Jia, *supra* note 4; *'Buy My Book' Official Accused of Taking Bribes*, SHANGHAI DAILY reprinted at CHINA.ORG, (Nov. 21, 2011), http://www.china.org.cn/china/2011-11/21/content_23969449.htm.

[160] *Id.*

[161] Yang, *supra* note 3, at 115-134, 284-288.

[162] *Id.* at 13.

> companies, including foreign companies, to other Chinese pharmaceutical companies, who then used dressed-up versions of these documents to get similar drug approvals.[163]

Recall that we have seen three circumstances where a generics application may legally receive registration without triggering patent linkage: registering a generics chemical entity through a new drug application, registering a generics drug without the corresponding patent listing, and registering a drug before patent issuance.[164] While each of these strategies can be accomplished via legal means, fraud and bribery made these strategies more attractive. For example, Prof. Yang describes bribes to obtain new drug registrations:

> Precisely because it was easy to gain regulatory approval for "new" drugs, firms resorted to bribery and other means to get more and more versions of the same drug approved as "new drugs". There was little incentive to become truly innovative....
>
> To some extent, the regulators could mass approve large numbers of "new" drugs partly because they knew that these were copies of drugs that had already been tested in other countries.[165]

Fraud and bribery eliminate the cost of obtaining costly clinical trials required for new drug data applications, and the ease of registering an old drug as new avoids patent linkage all together. Since the 2007 scandal, the SFDA and Ministry of Health have tightened ethical requirements and the anti-fraud campaign continues even to the point of creating a bottleneck during the drug approval process.[166] But the

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[163] *Id.* at 8; *see also* ACCESS TO MEDICINES IN UNDER SERVED MARKETS: WHAT ARE THE IMPLICATIONS OF CHANGES IN INTELLECTUAL PROPERTY RIGHTS, TRADE AND DRUG REGISTRATION POLICY? 13 (DFID Health Systems Resource Center, Sept. 2004), *available at* http://www.hlsp.org/LinkClick.aspx?fileticket=GhWtGtcqCkk%3D&tabid=1643 ("The state drug regulatory agency is responsible for both drug registration and the development of domestic industry. As a consequence of its divided mission, there have been reports of data leakage, notwithstanding domestic laws guaranteeing six years of data exclusivity. This may be discouraging innovator companies from registering their on-patent drugs available in China.").

[164] It should be noted that none of these paths triggers patent linkage in the United States either—their rarity is a function of the economics and regulatory backdrop.

[165] Yang, *supra* note 3, at 16.

[166] Shengwu Yiyao Chanye Mianlin Zhiyue Chuangxinyao Shenpi Weihe Zheme Man? (生物医药产业面临制约 创新药审批为何这么慢？) (Aug. 15, 2011) Renmin Wang Renmin Ribao (人民网 人民日报) [people.com people's daily] . Available at: http://health.people.com.cn/GB/15416093.html ("郑筱萸事件发生后，有关部门从"怕出问题"的目的出发，生硬照搬各个发达国家的最高标准，并把这些标准叠加在一起，在新药审批上严上加严。这样一来，既增加了临床前实验申报的时间以及等待审批

effectiveness of these measures remains to be seen.

### *E. Non-Infringement*

As mentioned earlier, the SFDA took up the responsibility of assessing infringement around 2005, which necessarily means that the SFDA may at times approve a drug based on its own determination that no patents are infringed.[167] The SFDA describes its internal process as follows:

> Essentially, if the patent is on the compound/composition, it would be relatively easy to determine if there is an infringement. However, if the patent is for a "process," then SFDA feels it cannot and should not be put in the position of needing to make a determination, and will often approve the registration application if the generic (subsequent) applicant claims non-infringement and agrees to bear the legal liability of infringement.[168]

Absent a mandatory list in the Orange Book, patent linkage depends on the SFDA's infringement assessment that may differ from the parties' analysis or the eventual judicial analysis. This is especially true when the SFDA regulators are not trained in the complex law of patent infringement or have access to the broader technological field to assess the validity of these blocking patents.[169]

The effectiveness of linkage review is further suspect considering how overworked and under staffed the regulators are—in 2008, the center for drug evaluation at the SFDA had a staff of 120, compared to a staff of 2632, 530, 521 and 130 in the U.S., EU, Japan and Taiwan, respectively.[170] The headcount is less than 1/20 of that in the U.S., for a country with four times the population, which translates into a case

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时间，也提高了研发成本，许多企业"不堪重负. ").

[167] U.S.-China Joint Commission, *supra* note 46, at 4.

[168] *Id.*

[169] Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 25-26 (2009) ("In such cases, the agency responsible for safety and efficacy of drugs is suddenly charged with observing questions of patentability, infringement, and related intellectual property issues, for which it lacks competence."); *see generally* Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 91 (2004) (noting that patent registration linkage creates "a presumption of validity of pharmaceutical product patents which health authorities are neither empowered nor have the capacity to challenge "; SIPO above).

[170] Lin Chunxia (林春霞)， Guojiaji Yaopin Shenpin Zhuanjia Shuliang Buji Meiguo 1/20 (国家级药品审评专家数量不及美国 1/20)， （Mar. 04, 2011）, Zhongguo Jingji Shibao [China Economic], http://www.jjxww.com/html/show.aspx?id=189227&cid=331

load of 50 applications per regulator.[171] Such grueling workload necessarily impacts the time and attention an individual regulator can devote to review and uncover fraud and irregularities already discussed. These considerations are now moot since the addition of a statutory Bolar exemption in 2009 that superseded the linkage regulations, although one cannot shake the feeling that the SFDA's eager embrace of Bolar betrays a desire to get away from the linkage quagmire.

## V IS CHINA READY FOR PATENT LINKAGE?

Although Chinese regulators experimented with variations of the linkage regime during the last ten years, the linkage regulation on the book does not appear to block infringing drugs today. The previous sections show that even when SFDA actually withheld drug approval based on patent linkage, the implementation was haphazard at best. SFDA lacks clear authority to enable linkage, lacks the capacity to conduct patent evaluations and lacks the wherewithal to resist aggressive applicants. The failed linkage system also reflects what Peter Yu terms the "intellectual property schizophrenia"—the notion that policymakers and regulators sought both stronger and weaker IP protection to satisfy the contradictory desire for an innovation driven industry and greater public welfare.[172] Together, the administrative breakdown destined the linkage regulations to fail the basic test of being laws, much less achieving the balance between innovation and medical access. Indeed, Chinese linkage regulations illustrate every single one of the "eight ways to fail to make law" that Lon E. Fuller identified some 50 years ago.[173]

At this juncture, one cannot help wonder whether the failed linkage regulations are a blessing in disguise: not having a patent linkage system is certainly an option and the burden is on the proponent of the complex linkage regulatory regime to justify the health and financial cost it imposes on developing countries. India built a world class generics industry in the absence of pharmaceutical patent protection and linkage regulations.[174]

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[171] [Quanguo lianghui Ti'an] Han Chaozhong: Jiaqiang Guojia Yaopin Shenping JIgou Jianshe, Tuidong ZhanLuexing Xinxing Yiyao Chanye Kuaisu Kexue Youxu Fazhan (【全国两会提案】韩忠朝：加强国家药品审评机构建设，推动战略性新型医药产业快速科学有序发展). (April. 1, 2011), http://www.tj93.gov.cn/detail.asp?newsid=2286

[172] Peter K. Yu, *International Enclosure, The Regime Complex, and Intellectual Property Schizophrenia*, 2007 MICH. ST. L. REV. 1, 25-26 (2007), *available at* http://www.msulawreview.org/PDFS/2007/1/Yu.pdf.

[173] LON L. FULLER, THE MORALITY OF LAW (Yale University, 1964).

[174] Janice M. Meuller, *Taking TRIPS to India--Novartis, Patent Law, and Access to Medicines*, 356 NEW ENG. J. MED. 541, 541-42 (2007) ("In the absence of notable patent-

Canada enjoyed lower drug costs and a vibrant generics industry, both of which were undermined by its patent linkage system.[175] NGOs and commentators fear that patent linkage will restrict access to essential drug for lower income countries.[176] The linkage system imposes real public and private cost in exchange for the mere possibility of encouraging better drugs in the future. Yet the Chinese government appears to be betting on that possibility and aspires to create an innovation-based pharmaceutical sector comparable to that of the United States.

The National Medium- and Long-Term Science and Technology Development Plan declares that China should "join the ranks of innovative countries [by 2020], thus paving the way for China to become a world leader in science and technology by the middle of the 21st century" and identified drug innovation and development and the control and treatment of AIDS, hepatitis and major diseases as two of thirteen enumerated engineering megaprojects.[177] The desire to promote its innovation law matches the current stage of China's innovation capacity. Empirical study has shown pharmaceutical IP protection positively contributes to domestic innovation in countries with higher levels of economic development, education and economic freedom.[178] China appears to fall under this category of countries: It graduates more science and engineering undergraduates and PhDs than the U.S.; articles of Chinese origin made up

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law restraints before 2005, India developed a world-class generic-drug-manufacturing sector, spawning major generics firms such as Ranbaxy, Cipla, and Dr. Reddy's, in addition to hundreds of smaller firms.").

[175] Crowne & Mihalceanu, *supra* note 25, at 709 (noting that "generics experienced considerable growth and the prices of medicines decreased substantially" before the enactment of its Notice of Compliance linkage regime).

[176] Baker, *supra* note 33, at 343 ("Developing countries, pro-health policy makers, and activists alike must resist and raise the stakes against the registration juggernaut."); Chuang-Feng Wu, *Raising the Right to Health Concerns Within the Framework of International Intellectual Property Law*, 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141 (2010) (noting the potential of patent linkage to delay the timely entry of generics medicine and reduce the health policy flexibility of developing countries); James Love, *[e-drug] Linkage of Patents and Drug Registration*, ESSENTIALDRUGS.ORG, (Feb. 6, 2001), http://www.essentialdrugs.org/edrug/archive/200102/msg00010.php.

[177] China's national Medium-and Long-Term S&T Development Plan (2006-2010), quoted and translated in John Orcutt and Hong Shen, 40; *see generally*, Cong Cao, Richard P. Suttmeier & Denis Fred Simon, *China's 15Year Science and Technology Plan*, PHYSICS TODAY, Dec. 2006, at 38 & 43, *available at* http://www.levininstitute.org/pdf/Physics%20Today-2006.pdf.

[178] Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002*, 89(3) THE REVIEW OF ECONOMICS AND STATISTICS 436 (2007); *see* LI, *supra* note 27, at 145.

5.9% of all science and engineering publications in 2005, less than but comparable to Japan (7.8%) and more than double the amount from South Korea (2.3%) and India (2.1%); and it has the highest R&D intensity of the BRIC economics.[179]

High concept, innovation driven domestic companies have emerged in China.[180] Currently there are 24 novel chemical drug candidates in clinical trial that received patent protection both in China and either the U.S. or EU.[181]

For example, BeiGene Co., Ltd is a R&D based pharmaceutical company formed by tech entrepeneure John Oyler and U.S. National Academy of Science member Xiaodong Wang in 2010. With the stated mission "to become the Genentech of China", BeiGene has gathered experienced drug hunters previously playing leadership roles at Johnson & Johnson, Merck, GlaxoSmithKline, Eli Lilly and Sanofi among its management and scientific rank.[182] BeiGene's drug discovery effort targets cancer types particularly prevalent in Chinese and the Asian-Pacific population.

If BeiGene represents the Genentechs of China, other generics companies have moved up the value chain to develop new therapeutic entities, following the historical trajectory of 19th and 20th century "generics" formularies that became Merck, Smith Kline & Co., Eli Lilly, John Wyeth and Upjohn.[183] In "Imitation to Innovation in China", Yahong

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[179] JOHN ORCUTT AND HONG SHEN, SHAPING CHINA'S INNOVATION FUTURE: UNIVERSITY TECHNOLOGY TRANSFER IN TRANSITION 46, 50 & 168 (Northampton, Mass.: Edward Elgar, 2010) (detailing China's university technology and licensing system).

[180] *See generally*, LI, *supra* note 65, at 57-59 (discussing several examples of Chinese drug firms that are developing novel drugs); Sarah E. Frew, et al., *Chinese health biotechnology and the billion-patient market*, 26 NATURE BIOTECHNOLOGY 37-53 (2008), *available at* http://www.nature.com/nbt/journal/v26/n1/full/nbt0108-37.html.

[181] Jingzong Qi, Qingli Wang, Zhenhang Yu, Xin Chen & Fengshan Wang, *Innovative Drug R&D in China*, NATURE REVIEWS (May 2011), http://www.nature.com/nrd/journal/v10/n5/full/nrd3435.html (listing 24 novel chemical drug candidates currently in clinical trial with patent protection in China and either the U.S. or the EU).

[182] Daryl Loo, *BeiGene Brings Biotech to China: By Wooing Top Talent, BeiGene Hopes to Copy U.S. Drug Success*, BUSINESSWEEK (Jul. 7, 2011), http://www.businessweek.com/magazine/beigene-brings-biotech-to-china-07072011.html.

[183] Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 371-72 (2011) (noting that many of the pharmaceutical giants today were once purveyors of unpatentable formulary drugs mixed from known substances and joined early anti-drug patent efforts).

Li documented the rapidly transforming Chinese biotech field and enumerated several examples of incremental innovation in the Chinese pharmaceutical industry at the start of the 21st century, including a head and neck cancer drug H101, the first commercialized gene therapy in the world Gendicine and a HIV protein inhibitor sifuvirtide.[184] More recently, Jiangsu Hengrui Pharmaceuticals has been called the "undisputed leader of China's oncology market" and noted by Morgan Stanley analysts for its successful transformation from a generics player into an innovative drug company.[185] Simcere is a NYSE-listed Chinese pharmaceutical company focusing on branded generics as well as its own patented anti-cancer drug Endu.[186] Still other generics companies are creating incremental but novel improvements relating to existing drugs. Cosunter Pharmaceuticals in the Fujian Province recently began marketing a generics version of Lamivudine, a first line AIDS drug and chronic hepatitis B exclusively sold by GlaxoSmithKline previously.[187] In addition to overcoming GSK's patents, Cosunter's generics version is itself protected by a patent directed to a new crystalline form of the active ingredient developed by Cosunter.[188]

The innovation gap between generics companies and brand companies are shrinking also because brand drug companies are behaving more and more like their generics competitors. In an empirical study of patenting behavior under the Canadian patent linkage system, Ron Bouchard notes a "paradoxical drug approval-drug patenting linkage" whereby multinational brand companies are "focusing more on evergreening older products and on incremental drug development rather than breakthrough drug development."[189] Thus, while the drug market may segment along the lines of new drugs versus generics drugs due their differentiated regulatory

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[184] LI, *supra* note 65, at 34, 53-57.

[185] Bin Li, Sean Wu & Christopher Lui, *China Pharmaceuticals: Time to Look at the Neglected China Drug Sector*, MORGAN STANLEY RESEARCH ASIA/PACIFIC (Feb. 6, 2009), http://www.jbhealthcare.com/download/China+drug+sector.pdf.

[186] *Simcere Pharmaceutical Share Price*, PROACTIVE INVESTORS UNITED KINGDOM, http://www.proactiveinvestors.co.uk/companies/overview/9102/simcere-pharmaceutical-9102.html (last visited Jan. 13, 2012).

[187] Guochan Lamifu Ding Tuwei Yigan Yao Geju (国产拉米夫定突围乙肝药格局), Yiyao Jingji Bao (医药经济报), (April 20, 2011), available at: http://www.yyjjb.com/html/2011-04/20/content_140099.htm

[188] Chinese Patent No. 200910119632.9 (issued Dec. 08, 2010).

[189] Ron A. Bouchard et al., *Empirical Study of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals*, 8 NW. J. TECH. & INTELL. PROP. 174, 16 (2010); *see generally* Monika Sawicka & Ron A. Bouchard, *Empirical Analysis of Canadian Drug Approval Data 2001-2008: Are Pharmaceutical Players "Doing More With Less?"*, 3 MCGILL J.L. & HEALTH 87 (2009) (presenting empirical evidence showing extensive follow-on patenting and drug registration under the Canadian patent linkage system).

path, the distinctions between generics companies and innovative companies become increasingly blurry. The story of Viagra itself illustrates the convergence between opportunistic brand name companies and innovative generics companies. While Pfizer's sildenafil patent was blocking a dozen Chinese companies from copying Viagra, other brand pharmaceutical companies are stepping around the patent with me-too drugs drawn from the same chemical family as sildenafil—Cialis from Eli Lilly and Levitra from Bayer. Interestingly, Welman Company, a Chinese company famed for winning a protracted dispute against Pfizer over the use of Viagra-related Chinese trademarks "WeiGe", is using its hard-won mark with its own oral ED drug by reformulating phentolamine mesylate, a known vasodilator unrelated to Viagra.[190] These recent developments evidence the gradual shift of the Chinese pharmaceutical sector beyond the tipping point where stronger linkage protection no longer automatically favors foreign interests.[191]

Thus when it comes to technological capabilities and ambitions, the Middle Kingdom may have more in common with the North than the South. The spread of patent linkage to China outside formal treaty obligations, then, is as much about defensively heading off economic and geopolitical threats as it is about constructively adopting and absorbing successful regulatory regimes originated elsewhere.[192] In its constant search for examples of legal mechanisms to develop the market economy, Chinese policymakers have drawn a connection between the strength of the U.S. pharmaceutical industry with the Hatch-Waxman Act.[193] Even critics of

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[190] *See* LI, *supra* note 65, at 54 (characterizing Cialis and Levitra as "me too" drugs of Viagra); http://ipr.court.gov.cn/gd/bzdjz/201005/t20100507_107668.html (discussing Welman's use of the WeiGe trademark with phentolamine mesylate).

[191] *See* Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U. L. REV. 131, 207-8 (2000) (anticipating greater IP protection in China once a local IP industry exist to benefit local economy).

[192] Randell Peerenboom, China's Long March Toward Rule of Law, _____; *see also*, James Thuo Gathii, *The Neoliberal Turn in Regional Trade Agreements*, 86 WASH. L. REV. 421, 474 (2011) (discussing constructivism as an explanation for the global spread of neoliberal ideals, including that of strong IP rights embodied in patent linkage). Prof. Gathii notes that "government officials in developing countries have adopted neoliberal reforms because they believe that such reforms are preconditions to achieving increased economic growth and efficiency in the public sector" and that "officials in developing countries are often passive imitators [that] rationally resort to neoliberal ideals." *Id.* at 412-13.

[193] Halverson, *supra* note 45 at 353 ("China's government has aggressively moved to create legal institutions to support the development of a market. The CCP's emphasis on legal reform dates back to Deng Xiaoping's "two hands" policy, which called for the development of the economy on one hand and the strengthening of the legal system on the other."); See Shen Han & Xu Huai-fu, Yaopin Zhuce Zhong Zhuanli LIanjie Wenti de

the Hatch-Waxman Act and its Canadian counterpart do not ask for the scrapping of these laws but instead target the improvement of specific features.[194] Might a better designed linkage system not similarly balance the competing interests in the Chinese pharmaceutical marketplace to foster innovations with a long return horizon and separate incremental improvers from the horde of slavish copiers?[195]

## VI TOWARDS A DEVELOPMENT-FRIENDLY LINKAGE SYSTEM

Should Chinese policymaker choose to further refine patent linkage, its pharmaceutical regulators need a better set of rules that are mindful of administrative limitations. The remainder of this article recommends five improvements that share the common strategy of minimizing the SFDA's exposure to subjective patent analysis while replacing imprecise guidelines with objective standards that are intelligible to the applicants, observable by the SFDA and reviewable by auditors. Specifically, drug regulators should: (1) narrow the scope of linkage to generics applications covered by the drug-patent registry; (2) update and reorganize the drug-patent registry; (3) require generics applicants to furnish detailed declarations and share the basis of its non-infringement contention with the innovator; (4) implement litigation triggers for parties to initiate (and possibly resolve) patent disputes prior to market approval; and (5) mandate an automatic stay period that sets the outer bound of regulatory delay and ensures that parties have a pre-defined time to resolve patent disputes. Together, they aim to improve the enforceability of the linkage regulations and create a platform within which policymakers can further fine-tune the balance of public and private interests.

### *A. Narrow Linkage Scope*

The current patent linkage regulation spans all drug applications that are not tied to a reference drug. The breadth demands a search based regime whereby the generics applicants should conduct a thorough freedom-to-

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Taolun, (药品註册中专利链接问题的探讨), [Discussion on the Patent Linkage Problems in Drug Registration], Yazhou Shehui Yaoxue, (亚洲社会药学), 2008, 3(1), 17 (praising the relatively refined patent linkage within the Hatch-Waxman Act and its positive contribution to the pharmaceutical industry).

[194] Crowne & Mihalceanu, *supra* note 25, at 723 ("We therefore suggest that the NOC Regulations should work in concert with the Patent Act, rather than on their own. This change would strike a balance between pharmaceutical patent protection and access to cheaper medicines while taking into account the realities of the modern pharmaceutical game and the public interest.").

[195]

operate search and the SFDA must perform a separate search to verify the result in order to truly enforce the last. This is an unrealistic demand and lacks measurable objective criteria, which in turn exposes the SFDA to extralegal sways, causes inter-agency conflicts with the patent administration, and creates an insidious divergence between the law as written and the law as administered.[196] Regulators should trim back the scope of China's patent linkage to cover only generics applications that rely on the data and approval of an innovator drug and for only those patents listed in the drug-patent registry. As discussed earlier, the generics companies are required to address patents listed in the drug-patent registry and only those patents as a precondition of approval. China is an exception.

Under the proposed narrower coverage, the SFDA need not conduct complex and subjective patent analysis that detracts from its health and safety function. Generics applicants need not perform open-ended patent searches that are never 100% certain. New drug applications that generated its own clinical trial data can dispense with regulatory IP oversight. Not only are the costs reduced, they are also placed on the correct cost bearer—only those who took advantage of the innovator's clinical trial data are subject to the regulatory patent review.

A narrow but objective and reviewable linkage system breaks a negative feedback cycle that erodes the psychology of long term IP compliance. Professor Peter Yu points out that the "key preconditions for successful intellectual property reforms include" among others, "a consciousness of legal rights, [and] respect for the rule of law."[197] A patent linkage that is overboard to the point of being unenforceable threatens to replace the respect for law and legal consciousness of applicants with a fatalistic opportunism: Since total compliance is as impossible as enforcement, a reasonable drug applicant should do what is expedient and hope that its registration sails through. And once an applicant decides to take liberty with Articles 18 and 19, the legal force of the remaining health and quality measures also appear less obligatory. Pruning back the unenforceable coverage and grounding it in easily ascertainable objectives enhances the respect for SFDA regulations *in toto*, including the portion of the linkage

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[196] Commenting on the challenges of vague Chinese laws generally, Prof. Halverson notes: "[T]hose vested with broad discretion to interpret and implement the laws tend not to be neutral but rather are influenced by a range of extralegal factors, including the political influence of the CCP, corruption, and the traditional importance in Chinese culture of personal relationships (guanxi)." Halverson, *supra* note 45, at 353.

[197] Yu, *supra* note 155, at 20.

law governing generics submissions.

An overbroad linkage may appease China's foreign trade partners and elevate China's IP reputation in the short run. Developing countries have been noted for adopting TRIPs compliant IP legislations while under-enforce the adopted law.[198] But this strategy creates unrealistic expectations among multinational corporations generates unnecessary trade friction in the long run. When an infringing drug inevitably slips through the registration process, the irregularities may become a source of legal complaints against the SFDA and China. Such complaint in fact occurs with some frequency during the JCCT meetings[199] or, when the heat of Washington politics turns to China, critical studies at the ITC at the behest of Senate members.[200] Companies that have invested in China can also move elsewhere, should it become clear that the cost of infringement turns out greater than what they anticipated.[201]

To be sure, applicants in China have the tendency to submit a generic drug under a new drug application for reasons outlined in section IVA. It is tempting to invoke patent linkage to block these "new" generics. But better regulatory tools exist to curb such filings. If the drug applicant used stolen or fabricated clinical data to submit a new drug application for a pre-existing pharmaceutical substance, the correct remedy is to punish the fraud or plagiarism itself just as if it had falsified any other clinical data, regardless of whether any patent is infringed.[202] Alternatively, should a

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[198] Rachel Brewster, *The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property*, 12 CHI. J. INT'L L. 1, 25 (2011) ("If a state enacts the required laws and yet the territory continues to have a high level of intellectual property infringement (perhaps the same level as before the enactment of the TRIPS required legislation), is the state in compliance with its TRIPS obligations? The answer seems to be yes.").

[199] U.S. – CHINA JCCT PHARMACEUTICALS AND MEDICAL DEVICES SUBGROUP MEETING SUMMARY (Beijing, China, March. 28-29, 2006), *available at* http://ita.doc.gov/td/health/mar06JCCTSummary-%20TheFinal%20didacted.pdf ("Some companies illustrate that at the same time, or shortly before their own marketing approval, up to 60 generics were approved using the originator's own clinical data (reliance of generics on innovator's data) whether under AP, patent or accelerated review by SFDA.").

[200] ITC Study, *supra* note 137 at I ("This is the first of two reports requested by the U.S. Senate Committee on Finance (Committee) on the effects of IPR infringement and indigenous innovation policies in China on U.S. jobs and the U.S. economy.").

[201] Nan Sze Ling, *Thailand's Ineffectual Intellectual Property Regime: A Trial and Error Approach to Encouraging Foreign Direct Investment Technology Spillover*, 24 N.Y. INT'L L. REV. 99, 153 (discussing the decisions of Sony and Canon to move key production process from China back to Japan in order to protect IP assets).

[202] *See supra* Section IVD.

generic company submit the appropriate toxicity and efficacy data obtained in an independent clinical test, the company is not a free-rider of the innovators' clinical trial and therefore outside the purview of the policy rationale for patent linkage. In the United States, a new drug application using independently obtained data never triggers patent linkage under the Hatch-Waxman act even if the drug is "generic" (previously approved for another company) or possibly infringing.

### *B. Improve Patent Registry*

Under the narrower linkage scope, a robust patent registry becomes the foundation of patent linkage system on which all other regulatory features are built: Generics companies may rely on the notice function of the registration to invent around or otherwise challenge a known patent; innovators benefit from an automatic, albeit limited, barrier to generics entry for a set period or until the resolution of patent disputes; and drug regulators enjoy lowering information and agency cost of ascertaining whether a generics drug application encroaches on the patents of another. To this end, the substance and organization of the drug-patent registry must both improve.

The substance of the drug-patent registry should improve once it becomes the basis of linkage. Patent owners will be motivated to list their patents with accurate and complete information. Occasionally patent owners may hide the ball—listing some patents to trigger linkage block while hiding others to ambush a generics competitor in court.[203] To ensure the listing is as complete as possible, the patent law can treat listing on the registry as a pre-requisite for all injunctive reliefs such that any patent not listed on the registry (but could have been) cannot be the basis of injunctions before the SFDA or the courts.[204] And to avoid the over-listing of irrelevant patents, the listing application should require the patent owner to identify at least one claim that covers the protected drug and the reasoning for the coverage as Canada has done.[205] The state can even impose fines for baseless drug-patent listings: the linkage system in Australia imposes an AUD 10 million fines, while Canada requires the

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[203] Crowne & Mihalceanu, *supra* note 23, at 714-15 (discussing the danger in Canada that a generic maker cleared of regulatory linkage may be sued "in respect to patents not listed on the Patent Register.").

[204] *See also*, Peter Drahos, *"Trust Me" Patent Offices in Developing Countries*, 34 AM. J.L. & MED. 151, 172 (2008) (advocating the outright unenforceability of unlisted patents).

[205] Crowne & Mihalceanu, *supra* note 25, at 709 ("In 2006, amendments made to the NOC Regulations required listed patents to contain at least one claim to the medical ingredient, formulation, dosage form, or use for which approval was granted.").

patentee to pay lost profit to generics companies improperly delayed due to incorrect listing.[206] Other simple technical improvements include: audit and cross-reference the patent listings to drug applications to avoid problems of blank patent fields or incorrect patent-drug listings; provide a method for updating and correcting patent information, in order to streamline the process of correcting clerical mistakes or listing a patent granted after the initial drug approval; and automatically checking the data of a listed patent against the patent record at SIPO—especially with respect to the generation of the patent expiration date. Finally, the database should be updated regularly for it to become an actual resource for drug developers.[207] Two separate checks of the database between June 1, 2011 and December 31, 2011 returned 1,290 listings, suggesting that the database has not been updated in the last six months.[208]

Organizationally, the current drug-patent registry displays the raw input from SFDA approval applications. Therefore the same active ingredient can generate an excess of listing entries as it moves through the stage of clinical trial approval, new drug registration, and manufacturing or importation registration. This creates the situation where a search for Caduet and Tarceva yielded 28 and 30 entries respectively but both in fact were covered by only a few patents.[209] Instead the SFDA can aggregate this data to centralize the patent listing corresponding to each approved drug submitted by the innovator during the original approval process. This in turn allows generics companies to easily identify all patents relating to a drug instead of wading through a freedom to operate search or missing a patent record in the database due to listing or linking error (such as a patent for Tarceva is listed under Caduet).

### *C. Require Detailed Disclosure*

The broad and perfunctory non-infringement guarantee fails to provide the necessary notice to patent owners. It currently serves only one

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[206] *Id.* at 718; Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, SOR/2006-242, Oct. 5, 2006 § 8(4), amending § 8(4); Drahos, *supra* note 190, at 172 ("Section 26C of the Therapeutic Goods Act 1989 (Australia), for example, imposes a penalty of AUD 10 million to deter companies from using patents of doubtful validity as part of a strategy of preventing or delaying the registration of generic drugs.").

[207] See Shen Han & Xu Huai-fu, Yaopin Zhuce Zhong Zhuanli LIanjie Wenti de Taolun, (药品註册中专利链接问题的探讨), [Discussion on the Patent Linkage Problems in Drug Registration], Yazhou Shehui Yaoxue, (亚洲社会药学), 2008, 3(1) (suggesting that the SFDA should adopt the design and timeliness of the Orange Book).

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[209] *See supra* section IIIB.

purpose—to isolate the SFDA from potential disputes between patent owners and generics. Instead of being used as an administrative CYA memo, the guarantee should provide reasons why a drug approval candidate does not infringe patents listed in the drug-patent registry and serves as a notice to the patent owner.

A detailed disclosure and notice system serves three goals. First, a detailed non-infringement analysis can better inform the patent owner, promote earlier dispute resolution and head off unnecessarily patent litigation. This is especially true for process patents—there is often more than one way of synthesizing or using a drug, allowing generics companies to invent around patents and adapt a non-patented process or usage, but the SFDA lacks scientific expertise, manufacturing know-how and the personnel to adjudge whether one complex process infringes another complex process.[210] Sharing non-infringement contentions with the patent owner passes the information to those in the best position to evaluate the information. A 2002 FTC study of patent linkage in the U.S. hints at the benefit of a detailed non-infringement analysis: out of 104 generics applications asserting non-infringement, the patent owner declined to file suit in 29 instances.[211] Had the patent owners not obtained detailed reasons why the generics company is not infringing, they may well pursue litigation in some of these cases.

Second, the proposal improves agency transparency and credibility. Even if the SFDA faithfully and competently carry out its gatekeeper function based on the blanket non-infringement guarantee, users of the system (generics and innovators) cannot peer inside the black box to ascertain whether the SFDA properly performed its role. Thus, the current guarantee undermines the effort to promote intellectual property, ensure honest registration data and restore SFDA reputation.[212] Instead, the SFDA should demand detailed contentions from generics applicants and bring the patent owners onto the same page, to shed the farcical appearance of the non-infringement guarantee.

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211 THE FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (Jul. 2002), at 14, *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

212 *See also*, WORLD HEALTH ORGANIZATION, MEASURING TRANSPARENCY IN MEDICINES REGISTRATION. SELECTION, AND PROCUREMENT: FOUR COUNTRY ASSESSMENT STUDIES, (2006), at 19, *available at* www.who.int/medicines/areas/policy/goodgovernance/Transparency4CountryStudy.pdf. (recommending "transparent structural and process arrangements" to combat corruption in the pharmaceutical regulation system).

Third, a detailed statement of non-infringement based on the drug-patent listing restores the currently misaligned incentive that depends on the generics companies making statements against self-interest: a generics company has no incentive to conduct a thorough patent search or to disclose potentially relevant patents because a good search can only harm the prospect of approval. Instead the current regulation amounts to a tacit invitation for misrepresentation and fraud, perversely rewarding those applicants who perform a perfunctory patent search or deliberately withhold patent information from the SFDA through fraud, cover-ups or omission. Under the proposed system, a generics company has every interest to explain why a drug-patent listing does not block its proposed drug candidate and rewards "good" generics applicants who took the time to invent around existing patents or to expose weak patents. It can ultimately improve the overall data stewardship and encourage applicants to engage with formal channel of resolving IP disputes.

### *D. Implement Litigation Trigger*

Chinese drug regulations such as the SFDA should play a limited administrative role while transferring the actual patent conflicts to the patent specialists. Instead of assessing infringement issues on its own, the SFDA merely needs to activate a statutory litigation trigger that creates jurisdiction in SIPO and People's Courts to hear patent disputes between the generics and innovators companies. In the meantime, the SFDA can continue to carry out drug safety and quality examination in parallel and grant market approval after the innovator prevails or after certain time allotted for patent dispute has lapsed, without conducting patent assessment itself.

Patent linkage need not pit drug regulators against thorny infringement issues. As described earlier, the U.S. patent linkage process occurs without discretionary input from the FDA. The innovator of a drug chooses which patents to list in the Orange Book. If the generics company asserts that these patents are invalid or not infringed, it is up to the innovator company to initiate litigation in the Federal district court. The FDA must withhold generics approval for 30 months or a decision favorable to the generics company, whichever occurs earlier. Under the detailed and restrictive statutory framework, the FDA acts as a bulletin board, a mail drop and a time stamp with very little discretion on substantive issues of patent validity and infringement—leaving the resolution of patent disputes to the courts.

The benefit of creating a civil litigation trigger to pass off linkage-related disputes is three fold, when compared to a system whereby the drug administrators resolve linkage disputes "in-house." First, it removes the tension between SFDA's capacity and its responsibility. The SFDA no longer needs to tackle thorny infringement issues in excess of its statutory authority, technical expertise or human resource. The SFDA views regulatory IP protection with suspicion, possibly out of fear for being held accountable for IP-related administrative infractions or being used as a pawn in business gamesmanship.[213] Perhaps for these concerns, the SFDA experimented with the watered-down patent linkage system and gingerly managed its IP gatekeeping function.[214] Yet the weak linkage system, implemented willy-nilly, exacerbates abuses and creates administrative uncertainty that ultimately contributed to the gutting of the patent linkage system since 2009. The fear became a self-fulfilling prophecy. A more limited and precise role also shrinks the gap between the linkage task and SFDA's health and safety mandate.

Second, consolidating patent disputes in the usual venue of SIPO and People's courts fosters uniformity and finality. The SFDA's assessment of patent issues has no preclusive effect and a later judicial or administrative decision can contradict SFDA's infringement analysis, especially when the SFDA confessed a lack of expertise (such when it assessed process patent issues in the past).[215] For another point of comparison, the Canadian linkage legislation forces its drug administration to conduct independent patent infringement review similar to what the SFDA had undertaken in 2005.[216] Critics of Canada's system have similarly advocated for a linkage design that consolidate linkage related issues in the courts, in order to avoid inconsistency and uncertainty when the decisions of the Canadian health authority conflict with subsequent judicial decisions.[217] Likewise, the

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[213] Shen Han (沈晗)，Xu Huaifu (徐怀伏)， Yaopin Zhuce Zhong Zhuanli Lianjie Wenti de Taolun （药品注册中专利链接问题的讨论）[discussion on the Patent Linkage Problems in Drug Registration], Yazhou Shehui Yaoxue (亚洲社会药学)[Asian Journal of Social Pharmacy] (2008, 3(1))， available at: www.asianjsp.com/qikan/manage/wenzhang/AJSP2008-0104.pdf; Reichman, *supra* note 152, at 25-26 (cautioning against the abuse of regulatory approval where "the patent holder can short circuit both an infringement action and the generic producer's process of marketing approval by reaching above their heads, so to speak").

[214] *Supra* note ____.

[215] *Supra* note ____.

[216] Crowne & Mihalceanu, *supra* note 23, at 693.

[217] *Id.* at 713-14 (discussing Canadian cases where drug administrator and courts rendered conflicting patent determinations).

SFDA should defer patent issues to SIPO and People's courts and reduce disorder in the marketplace whereby SIPO or People's courts contradicts the finding of infringement or non-infringement before the SFDA. In addition, SIPO and the IP specialists within the judicial branch have had time to build professionalism and competence.

Third, SFDA will be shielded from corrupting influences exerted by pharmaceutical companies that undermined administrative integrity in the past. Against this economic backdrop, the discretion to assess complex patent questions recalls the same rent seeking opportunity that brought down the former SFDA Commissioner Zheng Xiaoyu in 2007 and Deputy Commissioner Zhang Jingli in 2010.[218] As Zheng Xiaoyu lamented in his last testament before his execution: "I learned a valuable lesson from my tragedy—that is—as a bureaucrat it is better not to be one with a weighty position. More power is not always better."[219] A predictable litigation initiated by the parties and adjudicated outside of the SFDA divests excessive discretion from drug regulators and helps disperse this toxic bloom of centralized power, enormous profit and unreviewable decisions.

### *E. Define Automatic Stay*

Chinese drug regulators should consider instituting an automatic stay. An automatic regulatory stay such as the 30 months stay under the Hatch-Waxman Act allows tribunals an opportunity to resolve patent disputes in order to protect the interest of the patent owner without excessive delay to the drug approval process.

Regulators can set the outer bound of the stay based on the typical duration of patent litigation in China, while being mindful of the SFDA approval pendency. At present Chinese courts of the first instance are required to resolve domestic patent infringement disputes within one year of case filing although no strict time limit exists for cases involving foreign parties and can take longer.[220] A validity re-examination at the Patent Re-

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[218] *See supra* notes 159 & 160.

[219] Zheng Xiaoyu Xingqian "Huihen de Yishu: Gantan Dangguan Buhaowan (郑筱萸刑前"悔恨的遗书"感叹当官不好玩), （July 16, 2007）, http://www.stnn.cc/china/200707/t20070716_575961.html; Zheng Xiaoyu Yishu Cheng Dangguan Yao Fuzeren Jianchazhang Poxi Gaojie Xiashu (郑筱萸遗书称当官要负责任检察长剖析告诫下属 ), (Sep. 07, 2007), http://news.xinhuanet.com/politics/2007-09/07/content_6678266.htm

[220] Freshfileds Bruckhouse Deringer, Patent Litigation in Asia: People's Republic of China, (Dec. 2007), at 1, http://www.freshfields.com/publications/pdfs/2007/dec19/20496.pdf.

examination Board of SIPO generally takes up to twenty-four months to resolve.[221] The twenty-four month timeline also echoes the current article 19 of the 2007 Measure on the regulatory pendency side, which permits generics companies to submit an application two years before patent expiry.[222] Others put the approval time to approximately 18 months.[223] A stay of 18 to 24 months appears to be a reasonable time period to expect an initial verdict for patent disputes. Regulatory review can proceed in parallel while the status of the patent is being resolved, which in turn reduces the de facto delay caused by the stay while the patent dispute is being resolved. The length of stay also doubles as a policy dial which can be shortened to favor generics applicants or lengthened to favor patent owners, as Chinese lawmakers and regulators will ultimately decide for themselves.

An automatic stay of fixed length immunizes the SFDA against strategic behavior by both patent owners and patent challengers. The patent owner cannot drag on the patent dispute endlessly in the hope of blocking market approval and entry. For example, the initial validity challenge against Welman's antibiotics patent started in 2002 and lasted until 2006.[224] During the invalidation, Welman and its subsidiary could not agree on who actually owned the patent and, as a result, the invalidation was stayed pending the resolution of the ownership dispute (presumably because the invalidation proceeding must identify the correct patent owner).[225] The ownership dispute delayed the resolution of the validity challenge by three

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[221] *Id.* at 2; Bai, Wang & Cheng, *supra* note 101, at 453 ("Generally, it takes about six months to two years from filing a petition to obtaining a decision from the PRB, depending upon the workload in the relevant art units within SIPO.").

[222] Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Measures for the Administration of Drug Registration] (promulgated by the St. Food & Drug Admin., effective Oct. 01, 2007 ) (China) Art. 19 (对他人已获得中国专利权的药品，申请人可以在该药品专利期届满前 2 年内提出注册申请[applicants can file registration two years before the registered Chinese patent's expiry.]) available at: http://www.sda.gov.cn/WS01/CL0053/24529.html

[223] Jingxi Ding, Yajiong Xue, Huigang Liang, Rong Shao & Yongfa Chen, *From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies*, 6(2) J. TECH. MGMT. INNOVATION (June 2011), *available at* http://www.scielo.cl/scielo.php?pid=S0718-27242011000200001&script=sci_arttext (citing D. Chenoweth, *Is More Really Less in China's New Drug Approvals?*, 10(17) DRUG DISCOVERY TODAY 1140-1142 (2005)).

[224] See Fei Na(斐娜), Guanyu Yaopin Zhuce Zhong de Zhuanli Wenti de Anli Fenxi 9 关于药品注册中的专利问题的案例分析), Masters Thesis, 兰州大学, Lanzhou University, 15-16 (April 7, 2010)

[225] Zhuanlifa Xze, (专利法细则),[Substantive Patent Law] (China), Art. 18 Implementation regulations of the patent law permits the SIPO to stay an invalidation proceeding if the ownership of the patent is in dispute.

years.[226] One commentator who reviewed the Welman dispute suspected that the ownership dispute was an artificial crisis engineered by Welman to delay the invalidation of a weak patent.[227] A predetermined period of stay avoids the problem of indefinite hold up and takes away a patentee's ability to block market entry with procedural abuses.

A stay of fixed duration also curtails abuse on the generics side. Without a stay, we can expect generics companies to redouble their influence with the hope of gaining approval and flooding the market before People's court can render its judgment. A predetermined period of stay thus shields the SFDA from economic pressure, removes an unnecessary exercise of public authority, and affixes parties' expectations.

## VII CONCLUSION

Debates of patent linkage regulations have often been framed as a battle fought along two policy axes: the public welfare axis between future health innovation and present health access or the private industrial axis between branded companies and generics companies. This perception is more likely to be true in mature regulatory states such as the United States and Canada where administrative apparatus has the competence and authority to discharge the demands of linkage law. Many commentators have also argued convincingly that patent linkage is inappropriate for low-income countries in Africa and Latin America, a point that even the U.S. government has acknowledged since 2007.[228] To many of these countries, patent linkage is a poison that they are forced to swallow. The effect of linkage regulations is easier to anticipate when a country's role in the global pharmaceutical supply and consumption chain remains in a static setting in which innovator countries remain innovators and drug consuming countries remain consuming countries.

As for the remaining middle-income countries undergoing economic transition, China's experience provides a much needed data point for examining the importation and domestication of linkage regulations. This article highlights two underexplored dimensions. First, it highlights the question of "what *type* of innovation" does a country intend to promote.

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[226] See Fei Na (斐娜), Guanyu Yaopin Zhuce Zhong de Zhuanli Wenti de Anli Fenxi 9 关于药品注册中的专利问题的案例分析), Masters Thesis, 兰州大学, Lanzhou University, 15-16 (April 7, 2010) (reviewing the timeline of the Welman patent invalidation).

[227] See Fei Na, 斐娜 关于药品注册中的专利问题的案例分析 Masters Thesis, 兰州大学 Lanzhou University, 9 (April 7, 2010).

[228] [[ending the drug apartheid; Reichman, at 28-29; 10 JINTECL 921, 962, 965]]

In these developing countries with credible R&D capacity, patent linkage offers a tool to reward generic improvers that engage in their own incremental innovation and discourage generic imitators that slavishly copy the product of another. It matters little whether we label these incremental improvers "generics" or "brand" companies. The better domestic companies have begun to move up the value chain and flex their IP muscle in the process, as they grow accustomed to initiating patent challenges and building their own patent portfolios. These improvers may actually welcome patent linkage regulations that help differentiate their business model from the rest, in order to fight the other poison of rampant copying and free-riding in the China's pharmaceutical industry.

Second, it highlights the importance of a professional administration and a realistic legal design and shows what can go wrong in their absence. Countries exploring the linkage regime should not take regulatory maturity for granted. In this regard, innovation and drug access stand and fall together: it is unrealistic to expect a drug agency to protect intellectual property when it lacks the wherewithal to protect health and safety. The history and operation of patent linkage described in this article highlights the importance of designing enforceable laws and maintaining the credibility of the agency such that the linkage system will cure, not kill, the domestic pharmaceutical sector.

The greatest reward of examining China's linkage regulations, then, is to open a discursive space of fewer extremes: the distance between formerly dialectical concepts of imitation and innovation shrinks, and present health needs not lock horn with future innovation in a game of zero sums. As China busily explores this space for the next iteration of its linkage regulations, there is hope that it can find a nuanced and pro-development design freed from the confines of bilateral treaties on the one hand, and entrenched business interests on the other.