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THREE MAJOR PROBLEMS THREATENING MULTI-
NATIONAL PHARMACEUTICAL COMPANIES DOING
BUSINESS IN CHINA[†]

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Multi-National Companies (MNCs) in the pharmaceutical industry today face formidable challenges in China, the world's second-largest pharmaceutical market after the United States. Not only is China the world's largest source of counterfeit and substandard drugs, Chinese authorities have also recently targeted MNCs as part of a crackdown on bribery and competition law violations. In addition, China has a number of technology transfer laws that seem designed to force MNCs to provide uncompensated access to their proprietary technology protected by patents and trade secrets. All of these problems can be traced to China's rising nationalism and protectionism in its dealings with foreign companies and nations in international business and trade. These are daunting problems, but while MNCs focus their efforts on short-term technical solutions, only a long-term approach focusing on legal and political reform can provide a lasting solution.

I.	Introduction	47
II.	Counterfeit, Substandard Drugs and APIs	51
	A. Looking More Closely at "Counterfeit" Drugs	52
	B. Enforcement Barriers	55

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1.	Modern Complex Global Supply Chains.....	55
2.	Local Protectionism and Uncooperative Chinese Enforcement Authorities	57
3.	Competing and Overlapping Bureaucracies	59
III.	Crackdown on Commercial Bribery and Anti- Competitive Behavior	61
A.	Commercial Bribery.....	62
B.	Price-Fixing under the Anti-Monopoly Law	64
IV.	China's Policies in the Area of Patents and Technology Transfer	66
A.	China's Six-Year Data Exclusivity Protection	66
B.	China's Requirement That Clinical Trials to be Conducted in China.....	70
C.	China's Compulsory Licensing Provision	73
V.	China's Rising Nationalism and Protectionism.....	75
VI.	Conclusion.....	76

I. INTRODUCTION

Multi-National Companies (MNCs) in the pharmaceutical industry have been drawn to China because it currently has the world's second-largest pharmaceutical market after the United States,¹ but in recent years they have found themselves confronted with difficult challenges created by China's rising nationalism and protectionist policies. This Article identifies and examines three of the most significant challenges faced by MNCs. Together, they pose a formidable hurdle that must be addressed in order to secure the long-term desirability of the People's Republic of China (PRC) as a place to do business in the pharmaceutical sector. MNCs do not appear to fully understand the complex causes of these problems, hampering their ability to devise effective solutions.

1. See *2016 Top Markets Report, Pharmaceuticals, Country Case Study: China*, INT'L TRADE ADMIN, https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_China.pdf (last visited Jan. 8, 2018) ("China is the second largest pharmaceutical market in the world, forecasted to grow from \$108 billion in 2015 to \$167 billion by 2020, representing an annual growth rate of 9.1 percent.")).

First, China is the largest exporter of counterfeit and substandard drugs in the world.² It is also a major supplier of both genuine and substandard Active Pharmaceutical Ingredients (APIs).³ China makes counterfeit, substandard drugs and APIs for use in China⁴ and, perhaps more importantly, for export to countries around the world.⁵ These counterfeit exports can cause serious health problems, even deaths, and can subject MNCs to liability for these injuries.⁶ In addition, counterfeits can cause damage to the business reputation of MNCs and the goodwill associated with their brands.⁷ MNCs and the U.S. government have found themselves stymied in efforts to identify, locate, and shut down counterfeiters in China producing these illegal products.⁸

Second, within China, PRC enforcement authorities are targeting MNCs in the pharmaceutical sector⁹ as part of a

2. See U.S.-CHINA ECON. AND SEC. REV. COMM'N (CESRC), 2014 ANNUAL REP. ON CHINA 133 (2014), https://www.uscc.gov/sites/default/files/annual_reports/Complete%20Report.PDF (hereinafter CESRC Report).

3. See *id.* at 128-31.

4. Problems caused by substandard drugs and APIs in China cause health and safety problems for Chinese consumers and threaten the security of the nation and the reputation of its leaders. As a result, these crimes are dealt with by Chinese authorities in a swift and ruthless manner. See *China Vows Harsher Punishment for Production, Sale of Fake Drugs*, CHINA DAILY (Nov. 18, 2014), http://www.chinadaily.com.cn/china/2014-11/18/content_18937605.htm (noting harsher penalties for those who make fake and substandard drugs and “particularly heavier penalties” for the sale of such drugs to pregnant women, children, and patients in critical condition). See also *Global Trade in Counterfeit goods World Nearly Half a Trillion Dollars a Year – OECD and EUIPO*, OECD (Apr. 18, 2016), <http://www.oecd.org/industry/global-trade-in-fake-goods-worth-nearly-half-a-trillion-dollars-a-year.htm>.

5. See ROGER BATE & KAREN PORTER, AM. ENTER. INST. FOR PUB. POL'Y RES., THE PROBLEMS AND POTENTIAL OF CHINA'S PHARMACEUTICAL INDUSTRY 2-3 (2009), <http://ssrn.com/abstract=2342849>.

6. Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MED. 302, 302-03 (2005).

7. In a typical case, consumers who are harmed by counterfeits pursue the manufacturer of the legitimate product. This is often the only avenue of relief. The consumers do not know the identity of the counterfeiter whereas the identity of the legitimate product's manufacturer is right on the label of the counterfeit product. When the consumer discovers that the product is a counterfeit, this can lead to a loss of consumer good will for the legitimate brand. See Daniel C.K. Chow, *Counterfeiting in the People's Republic of China*, 78 WASH. U. L. Q. 1, 10 (2000).

8. See CESRC Report, *supra* note 2, at 136-37.

9. China has a set of national policies that appear discriminate against all MNCs in favor of domestic state-owned enterprises. See *generally* Daniel C.K.

crackdown on commercial bribery and violations of competition law under the Anti-Unfair Competition Law (AUCL),¹⁰ the Anti-Monopoly Law (AML),¹¹ and other related laws. Many MNCs have complained that China is using its competition laws to pressure them to alter prices.¹² In response, PRC enforcement authorities have accused MNCs of bribery and price gouging in violation of competition laws.¹³ MNCs are often subject to harassment and rough tactics (such as dawn raids) by competition law authorities,¹⁴ while Chinese competitors are not being punished even though they have engaged in similar or far more egregious conduct.¹⁵ This leads many MNCs to believe that they are the targets of selective and discriminatory treatment.¹⁶ The result of such discriminatory practices may include MNCs being forced to reduce prices for their drugs or erosion to their

Chow, *How China Promotes its State-Owned Enterprises at the Expense of Multinational Companies in China and Other Countries*, 41 N.C.J. OF INT'L L. 455 (2016). In the pharmaceutical sector, MNCs have complained that they are being targeted by PRC authorities for anti-competitive conduct even though Chinese state-owned companies have engaged in far more egregious conduct but have escaped prosecution. *See id.* at 483.

10. *See* Zhonghua Renmin Gongheguo Fan Bu Zhengdang Jingzheng Fa (中华人民共和国反不正当竞争法) [Anti-Unfair Competition Law of the People's Republic of China] (promulgated by the Third Session of the Standing Comm. of the Eighth Nat'l People's Cong., Sept. 2, 1993, effective Dec. 1, 1993). The AUCL has been undergoing extensive revisions but a new version of the law has not yet been enacted.

11. *See* Zhonghua Renmin Gongheguo Fan Longduan Fa (中华人民共和国反垄断法) [Anti-Monopoly Law of the People's Republic of China] (promulgated by the 29th session of the Standing Comm. of the Tenth Nat'l People's Cong., Aug. 30, 2007, effective Aug. 1, 2008).

12. *See* Michael Martina, *Exclusive: Tough-Talking China Pricing Regulator Sought Confessions from Foreign Firms*, REUTERS (Aug. 22, 2013, 1:12 AM), <http://www.reuters.com/article/us-china-antitrust-idUSBRE97K05020130822>.

13. *See* David Barboza, *Drug Giant Faced a Reckoning as China Took Aim at Bribery*, N.Y. TIMES (Nov. 1, 2016), https://www.nytimes.com/2016/11/02/business/international/china-rules-glaxo-bribes-sex-tape-whistleblower-cautionary-tale.html?_r=0.

14. *See* Natasha Bertrand, *Why China is Raiding Foreign Companies at Dawn*, BUS. INSIDER (Jan. 16, 2015, 12:15 PM), <http://www.businessinsider.com/china-raiding-foreign-companies-in-anti-corruption-crackdown-2015-1>.

15. *See* Benjamin Shobert, *Three Ways to Understand GSK's China Scandal*, FORBES (Sept. 4, 2013, 10:00 AM), <https://www.forbes.com/sites/benjaminshobert/2013/09/04/three-ways-to-understand-gsks-china-scandal/#2d61bd4c55dc>.

16. *See id.*

competitive position in relation to Chinese companies in the same industry.¹⁷

Third, China has a web of policies that have led to technology transfer laws that effectively force MNCs to transfer their pharmaceutical patents to Chinese companies.¹⁸ For example, some Chinese laws may be designed to limit pharmaceutical patent protections. This lower level of protection, arguably inconsistent with China's commitments under the World Trade Organization,¹⁹ may result in proprietary information losing protection before the patent owner is able to reap the full rewards of its invention in China.²⁰ Once the protection ends, the valuable commercial knowledge generated by MNCs enters the public domain and is available to Chinese companies, which includes competitors of MNCs. Thus, from an MNC's perspective, these policies, resulting in a shorter term of protection, are equivalent to a form of forced technology transfer.²¹

While these may seem to be disparate and unrelated problems, their root causes can often be traced to a network of nationalistic and/or protectionist rules, policies, and attitudes by the PRC authorities. In other words, these are not fundamental business problems but political problems. Such issues have no easy short-term solutions, so multinational pharmaceutical companies doing business in China must be patient and be willing to take a long-term perspective.²² This Article examines each of these problems and demonstrates how they can be traced to certain features of the current Chinese political and bureaucratic system. The Article then suggests, in light of the root causes of these problems, certain approaches to effectively address them.

17. See, e.g., Bertrand, *supra* note 14 (discussing the possibility that China is "cracking down on foreign firms intentionally to favor domestic competitors").

18. See discussion and sources cited *infra* Part III.

19. See discussion *infra* Part IV.A.

20. See Shaoyu Chen & John Balzano, *China*, in LIFE SCIENCES L. REV. 90 (Richard Kingham ed., 5th ed. 2017).

21. In this context, technology refers to valuable commercial information, often protected by intellectual property rights. Technology transfer refers to the giving of access by the owner of the technology to a third party. See DANIEL C.K. CHOW & THOMAS J. SCHOENBAUM, INTERNATIONAL BUSINESS TRANSACTIONS: PROBLEMS, CASES, AND MATERIALS 309 (Erwin Chemerinski et al. eds., 3d ed. 2015).

22. See Benjamin Shobert, *Why Did One of the World's Largest Drug Makers Exit China*, FORBES (Feb. 3, 2014, 5:52 PM), <https://www.forbes.com/sites/benjaminshobert/2014/02/03/why-did-one-of-the-worlds-largest-generic-drug-makers-exit-china/#2683475019f4> (discussing Actavis' withdrawal from China based on the belief that it could not make an acceptable profit in China).

II. COUNTERFEIT, SUBSTANDARD DRUGS AND APIs

According to the United States-China Economic and Security Review Commission (CESRC), China is the largest producer of counterfeit pharmaceuticals in the world.²³ The global trade in counterfeit drugs is estimated to be between US\$23 and US\$24 billion per year,²⁴ but some estimates place the trade at a much higher \$75 billion per year.²⁵ The CESRC also reports that sixty-five percent of seized counterfeits worldwide and seventy-nine percent of all seized counterfeits in the United States can be traced back to China.²⁶ Counterfeit drugs are a global business. Estimates suggest that up to thirty percent of all drugs in the developing world are counterfeit.²⁷ Indeed, as recently as 2001, up to seventy percent of all drugs in Nigeria were counterfeit or substandard.²⁸ One MNC, Pfizer Inc., the manufacturer of the well-known drugs Viagra and Lipitor, claims that as many as sixty of its drugs are being counterfeited around the world.²⁹ Criminal organizations

23. See CESRC Report, *supra* note 2, at 133.

24. See Joshua Philipp, *Beware of Fake Prescription Drugs Smuggled from China*, EPOCH TIMES (Dec. 31, 2014, 10:34 AM), <http://www.theepochtimes.com/n3/1129598-beware-of-fake-prescription-drugs-smuggled-from-china/>.

25. See Kathleen McLaughlin, *Fake Drugs from China: What's Stopping a Cure for Malaria in China?*, THE ATLANTIC (June 11, 2013), <http://www.theatlantic.com/china/archive/2013/06/fake-fake-drugs-from-china-whats-stopping-a-cure-for-malaria-in-africa/276750/> (discussing the global counterfeiting trade run by organized crime and foreign governments, estimated at \$75 billion per year).

26. See CESRC Report, *supra* note 2, at 133. Note that the term "counterfeits" used by the CESRC may be a loose term, including substandard and contaminated drugs, as discussed in Part II.A *infra*.

27. See WORLD HEALTH ORG., COUNTERFEIT MEDICINES: AN UPDATE ON ESTIMATES (2006), <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>. Recent world estimates are notoriously difficult to locate due in part to the clandestine nature of the global counterfeit trade and the unavailability of data, and perhaps, due to the lack of cooperation of multinational companies that do not want to draw attention to the severity of the problem.

28. See Roger Bate, *The Deadly World of Fake Drugs*, FOREIGN POL'Y (Oct. 6, 2009, 5:15PM), <http://foreignpolicy.com/2009/10/06/the-deadly-world-of-fake-drugs/>.

29. See Barbara Moran, *Cracking Down on Counterfeit Drugs*, NOVA NEXT (Aug. 20, 2013), <http://www.pbs.org/wgbh/nova/next/body/uncovering-counterfeit-medicines/>.

have migrated from illegal narcotics to counterfeit drugs because the profits are high and the risks are low.³⁰

A. Looking More Closely at “Counterfeit” Drugs

The term “counterfeit” is often used imprecisely and loosely by the media, company executives, and non-legal experts to refer to both counterfeit and substandard drugs as well as low-quality or contaminated APIs.³¹ This can create confusion for legal experts studying the problem of counterfeiting. As a technical legal term, counterfeit drugs refer to drugs that copy a protected trademark or brand name.³²

In the modern global economy, many drugs are protected by at least two different intellectual property rights: (1) a trademark for the brand name and (2) a patent for the invention.³³ For example, Pfizer’s drug Viagra—the most counterfeited drug in the world—is protected in the United States and other countries by the trademark “Viagra,” which refers to both the brand name of the drug and the name by which it is known to most consumers.³⁴ The drug Viagra is also protected by a second intellectual property right, a patent for the invention, *i.e.*, a drug’s chemical formula.³⁵ In the case of Viagra and other well-known drugs (such as Lipitor, a cholesterol-lowering medication), a counterfeiter will use the trademark name, as well as the trademarked shape and color of the genuine product, without the consent of the trademark owner.³⁶

As a technical issue, a drug that copies a patented formula in its entirety or in part is not a counterfeit, a term reserved for

30. See Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J. L. & MED. 279, 285-86 (2006).

31. See CHARLES CLIFT, CHATHAM HOUSE: CTR. ON GLOB. HEALTH SEC., COMBATING COUNTERFEIT, FALSIFIED AND SUBSTANDARD MEDICINES: DEFINING THE WAY FORWARD? 2, 4-10 (2010), <http://www.ghd-net.org/sites/default/files/Combating%20Counterfeit,%20Falsified,%20and%20Substandard%20Medicines%20-%20Defining%20the%20way%20Forward.pdf> (discussing the lack of agreement on definitions for counterfeit, falsified, and substandard medicines, and defining counterfeit drugs as copies or imitations).

32. Cynthia Ho, *Global Access to Medicine: The Influence of Competing Patent Perspectives*, 35 FORDHAM INT’L L. J. 1, 11-12 (2011).

33. See *id.* at 9-13.

34. See Daniel C.K. Chow, *Lessons from Pfizer’s Disputes Over its Viagra Trademark in China*, 27 MD. J. INT’L L. 82, 82-83 (2012).

35. See *id.*

36. See *Why You Should Never Buy ‘Cheap Viagra’*, TREATED.COM, (last visited Oct. 29, 2017), <https://www.treated.com/erectile-dysfunction/viagra/how-to-avoid-scams>.

trademarks, but a patent infringement.³⁷ In the modern global trafficking of counterfeit drugs, counterfeits rarely involve a drug that completely copies the scientific formula of a genuine drug, so patent infringements are not usually at issue in counterfeit drugs.³⁸ In the case of Viagra, some illegal knock-offs contain trace amounts of the patented ingredients, while others contain no active ingredients at all.³⁹

Counterfeit drugs usually only use the trademark and do not attempt to copy the chemical formula of the drug protected by a patent.⁴⁰ Indeed, this is how the counterfeiter profits from the imitation.⁴¹ The counterfeit purports to be a genuine drug with active ingredients, but it generally only copies the brand name, thus allowing the counterfeiter to cut costs by using inexpensive or worthless substitute ingredients.⁴² As a result, the counterfeit drug may have no active ingredient or it may be comprised of an insufficient dosage or trace amounts of the real drug.⁴³ Similarly, counterfeits may be manufactured with dangerous substitutes or contaminated substances.⁴⁴ The counterfeit will also come in false packaging that imitates that of the genuine product.⁴⁵ It can be easier to make a pill containing sugar powder and put it in a false package than it is to put on a counterfeit Nike Swoosh on a pair of sneakers and or to add a counterfeit designer label to a luxury handbag.

The term “counterfeit” is also loosely used to refer to drugs of substandard quality.⁴⁶ As used by the media and non-legal experts,

37. See Ho, *supra* note 32, at 9.

38. Cf. *Background Information on Counterfeit Drugs*, BAYER (May 29, 2017), <https://www.bayer.com/en/counterfeit-drugs.aspx>. Patent infringements are a major issue in the case of generic drugs. In this context, generic drugs refer to drugs with the same or substantially similar scientific formula as the genuine drug, but which are sold at a steep price discount. The generic drug maker may sometimes argue that the generic version does not infringe the patent, that the patent is invalid, or has expired. See Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 111 n.155 (2013) (“Technically, the potential generic-drug maker must only certify that the patent is expired (or will expire) or that it is invalid or not infringed by the proposed generic drug.”).

39. Emily Hunt, *Fake Viagra, What You Need to Know*, ONLINEHEALTH (May 18, 2016), <https://onlinedoctor.lloydspharmacy.com/blog/fake-viagra-health-risks/>.

40. See Liang, *supra* note 30, at 285-86.

41. *Id.*

42. *Id.* at 289-90.

43. *Id.* at 283-85.

44. *Id.*

45. *Id.* at 289-90.

46. See *id.* at 284.

“counterfeit” also applies to genuine drugs that contain substandard or contaminated APIs.⁴⁷ China is the world’s largest manufacturer of APIs and exports large quantities that are used in pharmaceuticals manufactured around the world.⁴⁸ In 2008, Baxter International, Inc., used contaminated heparin, a blood thinning agent, in its blood thinning medication distributed in U.S. hospitals.⁴⁹ The contaminated drug led to 81 deaths in the United States.⁵⁰ The drug itself was genuine because it was produced under authorization by Baxter, but it contained a contaminated ingredient instead of pharmaceutical-grade heparin.⁵¹ The contaminated heparin was used in a drug distributed in the United States by Baxter, but the API was traced to a supply chain in China.⁵² About the same time, cough syrup containing a poisonous ingredient from China killed dozens of children in Haiti and Panama.⁵³ The ingredient mixed into the cough syrup was supposed to be glycerin, an API used in many products (including cough syrup and toothpaste), but instead was diethylene glycol, a cheap but poisonous substitute used in anti-freeze.⁵⁴ The deadly diethylene glycol was exported by Sinochem, a major Chinese state-owned enterprise.⁵⁵

The fallout from the deaths caused by contaminated drugs can create serious business problems for MNCs. In Baxter’s case, consumers filed hundreds of lawsuits against Baxter for the contaminated heparin,⁵⁶ damaging their business reputation as a reliable source of medications and costing Baxter substantial damages.⁵⁷ Overall, counterfeit drugs, substandard drugs, and APIs are a serious threat to an MNC’s brands and goodwill.⁵⁸

47. See Atholl Johnston & David W. Holt, *Substandard Drugs: A Potential Crisis for Public Health*, 78:2 BR. J. CLIN. PHARMACOLOGY 218, 219 (2014).

48. See CESRC Report, *supra* note 2, at 127.

49. See CESRC Report, *supra* note 2, at 136-37.

50. See *id.*

51. See *id.*

52. See *id.*

53. See Walt Bogdanich & Jake Hooker, *From China to Panama, a Trail of Poisoned Medicine*, N.Y. TIMES (May 6, 2007), <http://www.nytimes.com/2007/05/06/world/americas/06poison.html>.

54. See *id.*

55. See Walt Bogdanich, *FDA Tracked Poisonous Drugs, but Trail Went Cold in China*, N.Y. TIMES (June 27, 2007), <http://www.nytimes.com/2007/06/17/health/17poison.html>.

56. See CESRC Report, *supra* note 2, at 137.

57. See Bruce Japsen, *\$625,000 Judgement Against Baxter in 2007 Blood-Thinner Death Case*, CHI. TRI. (June 9, 2011), <http://articles.chicagotribune.com/>

The term “counterfeit,” as used by the media and non-legal experts, encompasses all of these various types of illegal products: counterfeits of trademarked brand names with trace amounts or no active ingredients, patent infringements, and genuine or unauthorized drugs using contaminated APIs.⁵⁹ The use of the term “counterfeit” to describe all of these problems can be confusing because it obscures the existence of multiple related problems in addition to counterfeiting. MNCs are faced not with one problem but with multiple problems, increasing the challenges they face in China.

B. Enforcement Barriers

Adding to the difficulties raised by the myriad of legal issues involved are a number of practical problems in the modern multilateral trading system and China’s political system that create barriers to the protection of the rights of multinational pharmaceutical companies. Set forth below are three of the most significant barriers.

1. Modern Complex Global Supply Chains

In the modern global economy, many countries, including the United States, often use foreign trade zones (FTZ), usually located near an airport or a seaport containing a customs point of entry, in order to facilitate international trade.⁶⁰ Imported goods must clear customs and the importer must pay a duty or tariff before the goods are released into the importing country’s internal market.⁶¹ An FTZ is a specifically designated area where goods can enter without the payment of customs duties.⁶² In the FTZ, the goods can be finished, assembled or reassembled, and repackaged.⁶³ A customs duty is paid when the goods leave the FTZ and then enter customs for the assessment of the duty after the additional work has been completed.⁶⁴ Once the goods clear customs, the goods can enter the country in which the FTZ is located. In other cases,

2011-06-09/business/ct-biz-0610-baxter-heparin-20110609_1_oversulfated-chondroitin-sulfate-animal-like-substance-scientific-protein-laboratories.

58. See Cockburn et al., *supra* note 6, at 304.

59. See Johnston & Holt, *supra* note 47, at 218.

60. See DANIEL C.K. CHOW & THOMAS J. SCHOENBAUM, INTERNATIONAL TRADE LAW: PROBLEMS, CASES, AND MATERIALS 193 (2d ed. 2012).

61. See *id.*

62. See *id.*

63. See *id.*

64. See *id.*

the goods can be shipped directly from the FTZ to another country and enter customs in the country of final destination.⁶⁵

For all imports, the customs authorities will determine the duties owed by the importer by identifying the country of origin of the goods as the tariff rate varies depending on the country of origin.⁶⁶ In the United States, federal law requires that the country of origin be marked on the goods in order to protect the consumer.⁶⁷ Because no tariff is due on goods that enter into the FTZ,⁶⁸ customs authorities do not require a country of origin determination before the goods enter into the FTZ.⁶⁹ Authorities have discovered that FTZs can be easily used to hide the true origin of the goods.⁷⁰ For example, drugs or APIs from China might enter the FTZ in Dubai, one of the most frequently used FTZs in world trade, to alter the source of origin.⁷¹ If the FTZ in Dubai is not closely supervised,⁷² the product can be repackaged in Dubai and the country of origin can be changed from China to another country—for example, it might be possible to label APIs from China as originating from Germany. The same process can be used in FTZs in other countries, such as European nations.⁷³ This allows for disguising the true origin of the product or the API, which makes tracing the source of substandard or fake drugs or APIs to their true country of origin an expensive, difficult, and time-consuming process. In some cases, it is not possible to trace illegal drugs to their true country of origin.⁷⁴

65. See Walt Bogdanich, *Counterfeit Drugs' Path Eased by Free Trade Zones*, N.Y. TIMES (Dec. 17, 2007), http://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html?_r=0.

66. See CHOW & SCHOENBAUM, *supra* note 60 at 195 (In the United States and other WTO countries, different tariff rates are applied to the same goods depending on the country of origin of the product. For example, the tariff rate on a computer product cannot be finally determined without reference to its country of origin. Depending on the country of origin, U.S. Customs might impose an agreed upon World Trade Organization tariff rate, a prohibitively high rate known as the statutory rate, or zero.).

67. 19 U.S.C. § 1304 (1999) (The consumer has the right to know the country of origin of the product as its origin often influences the decision by the consumer to purchase the product).

68. Bogdanich, *supra* note 65.

69. CHOW & SCHOENBAUM, *supra* note 60, at 193.

70. Bogdanich, *supra* note 65.

71. *See id.*

72. *See id.* It is not clear that Dubai customs authorities have jurisdiction to regulate the Dubai FTZ.

73. *See id.*

74. *See id.*

2. Local Protectionism and Uncooperative Chinese Enforcement Authorities

Even when the origin of an illegally produced drug or API can be traced to China, MNCs will find that local governments in China have an incentive to protect local industries, even if they are engaged in behavior of questionable legality.⁷⁵ PRC central authorities evaluate local governments by their economic output and exports, including counterfeits and substandard drugs.⁷⁶ This economic structure means that local governments have an incentive to protect exporters, including counterfeiters and makers of substandard drugs and APIs. These protectionist attitudes can result in uncooperative local enforcement authorities who refuse to bring enforcement actions, delay enforcement actions, or who might tip off illegal manufacturers to enforcement actions. Even when an enforcement action is brought, local enforcement authorities might impose insignificant fines and penalties that do not create deterrence.⁷⁷ This incentive structure also means that local authorities resist pressure from central-level authorities to crack down on counterfeiters.

The central-level enforcement authorities in Beijing have additional incentives to be less than cooperative with MNCs in locating illegal factories. Past cases indicate that central authorities are reluctant to disclose the location of counterfeiters even where clear wrongdoing appears to have occurred.⁷⁸ For example, after an extensive investigation, U.S. authorities were able to trace the source of the contaminated heparin to China.⁷⁹ Yet, the PRC authorities never disclosed the locations of where the contaminated heparin entered the supply chain, although they plainly had such information.⁸⁰ This information would have allowed U.S. authorities to press PRC central authorities to shut down the entry points. The same result occurred in cases involving poisonous

75. For a general detailed discussion of local protectionism in the context of counterfeit goods, see Daniel C.K. Chow, *Organized Crime, Local Protectionism, and the Trade in Counterfeit Goods in China*, 14 CHINA ECON. REV. 473, 473-84 (2003).

76. See DANIEL C.K. CHOW, *THE LEGAL SYSTEM OF THE PEOPLE'S REPUBLIC OF CHINA IN A NUTSHELL* 456 (3d ed. 2015).

77. See BATE & PORTER, *supra* note 5, at 3.

78. See, e.g., Bogdanich, *supra* note 55 (noting repeatedly instances in which Chinese authorities refused to cooperate in locating glycerin factories).

79. See CESRC Report, *supra* note 2, at 136-371.

80. See *id.*

substitutes for glycerin in cough syrup.⁸¹ The United States was able to determine that the poisonous substitute was produced in China, but was ultimately unable to pinpoint the exact source of the drugs in China due to resistance from uncooperative PRC authorities.⁸²

Why would Chinese central authorities be willing to hide the locations of illegal factories that produce APIs or drugs that cause deaths to consumers in foreign countries? This type of government behavior might not seem likely to occur in the United States, but China has a starkly different political system. In China, the political realities are that even where there is clear wrongdoing, central and local officials do not want to be found responsible for a dereliction of duty that would compromise their own interests in maintaining or advancing their careers.⁸³ If a central-level official were to disclose the location of an illegal factory, the disclosure might result in discipline of the factory owner, of the local officials in charge of supervision of the factory, or of the central-level official in charge of supervision of the local officials.⁸⁴ The official who disclosed the information might be subject to retaliation by the suspects or by their patrons who might be higher-level officials or Communist Party members.

If the illegal drugs caused deaths or injuries of Chinese citizens, Chinese consumers and media would likely demand punishment of those responsible. This political and social pressure would compel PRC leadership to act. But the situation is quite different when the harms or even deaths occur in a distant foreign country, outside the glare of the public and social media in China. In these cases, the Chinese public and media seem to show little interest or concern and the Chinese authorities do not feel compelled to act.

In the heparin case, for example, the Chinese authorities, while admitting that China was the source of the contaminated heparin,

81. See Bogdanich, *supra* note 55.

82. See *id.*

83. Cf. Eva Li, *Chinese Local Governments Admit Major Cover-Up of 2012 Flood Deaths*, S. CHINA MORNING POST (Mar. 30, 2017), <http://www.scmp.com/news/china/policies-politics/article/2083483/chinese-local-governments-admit-major-cover-2012-flood> (describing the confession as a “rare official admission of cover-up” and the government’s new transparency about casualties “has not filtered down to the local level where officials still tend to underreport or cover up death tolls because their career prospects could be hampered by large numbers of casualties in natural disaster or accidents”).

84. See *Government More Resolute in Fighting Dereliction of Duty*, CHINA.ORG.CN (June 11, 2004), <http://french.china.org.cn/english/government/97938.htm>.

never admitted to any responsibility for the deaths caused in the United States.⁸⁵ In the contaminated glycerin cases, Sinochem, a massive state-owned enterprise controlled by the Communist Party, was the exporter of the poisonous substitute, refused to disclose the location of its suppliers.⁸⁶ Any disclosure of the location of the factories and an admission of guilt or even negligence would have ensnared a number of Chinese Party officials in the ensuing scandal. These political realities indicate that those seeking to find the source of illegal factories in China face not only logistic hurdles (created by FTZs as discussed above), but also resistance from PRC enforcement authorities. MNCs might find this resistance to be difficult or impossible to overcome. If locating the source of counterfeit and substandard drugs in China proves difficult or impossible, then stemming the tide of these illegal exports could become an insurmountable problem.

3. Competing and Overlapping Bureaucracies

China has an immense and complex bureaucracy in many areas with layers of overlapping authority. In the pharmaceuticals arena, the China Food and Drug Administration (CFDA) supervises the manufacturing of drugs and APIs and enforces product and safety standards.⁸⁷ A pharmaceutical company that produces drugs or APIs is subject to supervision and regulation by CFDA.⁸⁸ In addition to pharmaceutical companies in China, many chemical factories also produced drugs and APIs.⁸⁹ Chemical factories are subject to oversight by the China Petroleum and Chemical Industry Federation (CPCIF), not CFDA; the CPCIF does not enforce the CFDA standards.⁹⁰ As a result, chemical factories can produce drugs and APIs that do not meet standards set by the CFDA and can export these products around the world.⁹¹

85. *Id.*

86. *See* Bogdanich, *supra* note 55.

87. *See About CFDA*, CHINA FOOD DRUG ADMIN., <http://eng.sfda.gov.cn/WS03/CL0756> (last visited July 23, 2017).

88. *See id.*

89. *See* Walt Bogdanich, *Chinese Chemicals Flow Unchecked onto World Drug Market*, N.Y. TIMES (Oct. 31, 2007), <http://www.nytimes.com/2007/10/31/world/asia/31chemical.html>.

90. *See About CPCIF*, CHINA PETROLEUM AND CHEM. INDUS. FED'N, <http://www.cpcia.org.cn/English/about.asp?n=2>.

91. *See* Bogdanich, *supra* note 89.

Why would the CPCIF be unwilling to cooperate with the CFDA in regulating the production of drugs and APIs? Again, political realities in China can intrude.⁹² Bureaucracies within China are often intensely competitive with each other. The CPCIF does not wish to cede power to CFDA and allow the CFDA to regulate its chemical factories. Similarly, the CPCIF does not wish to become a tool of the CFDA and enforce the CFDA's standards on its behalf. Instead, the CPCIF wishes to regulate its chemical factories as it sees fit and would like to protect or expand its sphere of power. A wider sphere of power means more resources, personnel, and status for the CPCIF within China's overall massive government bureaucracy. On the other hand, although the CFDA might wish to regulate chemical factories that produce pharmaceuticals, it has no clear authority to do so.⁹³ Chemical industries, under the jurisdiction of the CPCIF, would ignore the CFDA and any attempts by CFDA to expand its jurisdiction to include chemical factories would be met with strong resistance by the CPCIF. As a result, many chemical factories continue to produce drugs and APIs that do not meet CFDA standards and continue to export them to countries around the world.⁹⁴ In addition, exports by chemical factories or state-owned enterprises (such as Sinochem) create revenue that the CPCIF is reluctant to forgo. The end result of this overlapping bureaucratic structure is that chemical factories in China continue to produce substandard drugs and APIs at a prodigious rate for export to countries around the world without any effective supervision.⁹⁵

From the viewpoint of MNCs, this becomes a problem riddled with difficulties. Since this is an issue of bureaucratic in-fighting and political structure within China, MNCs have little influence or power to affect rivalries between powerful government entities. MNCs are involved in business and have little standing to raise issues involving the political structure of the PRC government. Moreover, these issues are both delicate and sensitive. Bureaucratic

92. Cf. JEREMY R. HAFT, UNMADE IN CHINA: THE HIDDEN TRUTH ABOUT CHINA'S ECONOMIC MIRACLE 178-82 (2015) ("The original plan was to have the CFDA be the master regulator But rival bureaucracies, with powerful protectors in the State Council and state-owned industries, resisted diminution [These agencies will] keep fighting bitterly over budget, resources, and authority. This kind of fragmented regulatory structure also leads to jurisdictional blind spots. Where there are loopholes in the law, agencies tend not to want to extend themselves beyond their prescribed authority.").

93. *See id.*

94. *See id.*

95. *See id.*

rivalries within the PRC government mean that entrenched interests will mount strong resistance to any reform of the current structure. For the foreseeable future, substandard drugs and APIs from chemical factories not subject to supervision by the CFDA seem likely to continue to pour largely unchecked into the international market.⁹⁶

III. CRACKDOWN ON COMMERCIAL BRIBERY AND ANTI-COMPETITIVE BEHAVIOR

In addition to dealing with the flood of counterfeits and substandard drugs and APIs from China, MNCs have in recent years faced regulatory challenges from competition law authorities in China.⁹⁷ In a highly publicized campaign against corruption, China has punished numerous Communist Party officials.⁹⁸ The crackdown on corruption, however, is not limited to government corruption, but has also been extended to corruption in business, particularly commercial bribery.⁹⁹ Under the Anti-Unfair Competition Law (AUCL), commercial bribery refers to the payment by a business entity to another business entity or to a Party or government official, in order to obtain a business benefit.¹⁰⁰ China has recently recognized the severity of commercial bribery (in addition to government corruption) and has begun to aggressively enforce anti-bribery laws against MNCs.¹⁰¹ China has also recently begun to accuse MNCs of other

96. China is the world's top producer of APIs so it would stand to reason that these APIs, often produced by unsupervised factories, will continue to pour into the world market. See CESRC REPORT, *supra* note 2, at 131 (describing China as the world's top producer of APIs, drug dyes, binding agents, gel capsules, and other inert substances).

97. See generally Daniel C.K. Chow, *How China's Enforcement of its Anti-Monopoly Law Poses Risks to Multinational Companies*, 14 SANTA CLARA J. INT'L L. 1, 1-8 (2015).

98. See Daniel C.K. Chow, *How China's Crackdown on Commercial Bribery Has Led to Less Transparency in the Enforcement of China's Anti-Bribery Laws*, 49 UC DAVIS L. REV. 685, 687 (2015).

99. Keith Bradsher & Chris Buckley, *China Fines GlaxoSmithKline Nearly \$500 Million in Bribery Case*, N.Y. TIMES (Sept. 19, 2014), <https://www.nytimes.com/2014/09/20/business/international/gsk-china-fines.html>.

100. See Zhonghua Renmin Gongheguo Fan Bu Zhengdang Jingzheng Fa (中华人民共和国反不正当竞争法) [Anti-Unfair Competition Law of the People's Republic of China] (promulgated by the Third Session of the Standing Comm. of the Eighth Nat'l People's Cong., Sept. 2, 1993, effective Dec. 1, 1993). ("Managers shall not use money or properties or the other methods to bribe to others in order to sell or purchase commodities.")

101. See Chow, *supra* note 98, at 688-89.

forms of anti-competitive behavior, such as price fixing or price gouging, abuse of intellectual property rights, and mergers and acquisitions that result in an abuse of monopoly power, also illegal under China's competition laws.¹⁰² In recent years, China has enacted new laws to deal with these various forms of anti-competitive conduct and has increased enforcement of existing laws.¹⁰³

A. Commercial Bribery

Although China was already underway in its anti-corruption campaign, it drew worldwide attention in 2014, when PRC enforcement authorities fined GlaxoSmithKline (GSK), a U.K. company, nearly \$500 million in a bribery case.¹⁰⁴ The case involved the largest bribery fine to date.¹⁰⁵ Commercial bribery is common in China, and now has progressed from simple payouts to more elaborate schemes set up to avoid detection.¹⁰⁶ One type of scheme involves the use of travel agencies.¹⁰⁷ Employees within the MNC work with an outside travel agency to organize trips, conferences, or other training sessions.¹⁰⁸ The trip might be one that never occurs, the expenses for the trip might be inflated, or the actual persons traveling on the trip might not be persons listed on the official itinerary.¹⁰⁹ The bill for these charges are provided to the MNC, which pays the travel agency the amount of the fictitious bill.¹¹⁰ The travel agency then funnels the extra cash received from the MNC to a recipient of the bribe.¹¹¹ According to

102. See generally Chow, *supra* note 97.

103. Commercial bribery is covered by Article 8 of the AUCL, a 1993 law currently under a multi-year revision, but the PRC has also enacted a specific judicial interpretation that deals with commercial bribery. See Guanyu Banli Shangye Huilu Xingshi Anjian Shiyong Falv Ruogan Wenti De Yijian (关于 □ 理商 □ □ □ 刑事案件适用法律若干 □ □ 的意 □) [Opinions on Issues Concerning the Application of Law in the Handling of Criminal Cases of Commercial Briberies] (promulgated by the Sup. People's Ct. and the Sup. People's Procuratorate, Nov. 20, 2008, effective Nov. 20, 2008), CLI.3.110862(EN) (Lawinfochina).

104. Bradsher & Buckley, *supra* note 99.

105. See *id.*

106. See *id.*

107. See *id.*

108. See David Barboza, *Glaxo Used Travel Firms for Bribery, China Says*, N.Y. TIMES (July 15, 2013), <http://www.nytimes.com/2013/07/16/business/global/glaxo-used-travel-firms-in-bribery-china-says.html>.

109. See *id.*

110. See *id.*

111. See *id.*

the Chinese media, GSK used travel agencies to funnel \$489.4 million to doctors working in state hospitals to induce these persons to purchase pharmaceuticals from GSK.¹¹² The GSK case drew worldwide media attention because of the record fine for its bribery scheme.¹¹³

From GSK's perspective, however, there were several issues with the case. China's doctors are underpaid and in the past have sought bribes in exchange for prescribing drugs from certain manufacturers.¹¹⁴ The practice is well-known in China, not just among pharmaceutical executives and state hospital administrators, but also to the general public.¹¹⁵ It is common knowledge in China that doctors receive a kickback from the pharmaceutical company when the doctor prescribes its medications.¹¹⁶ Moreover, GSK's competitors were also paying bribes to get their medications prescribed.¹¹⁷ GSK might have justified the scheme as a necessary tactic in the intensively competitive Chinese drug market and may have erroneously assumed that PRC enforcement authorities, well-aware of the common practice, would continue to ignore it. One sensational element in the GSK case was the suspended prison sentence of a British executive, who had voluntarily returned to China for the trial.¹¹⁸ The British executive left China,¹¹⁹ but the mere prospect of serving jail time in a Chinese prison must have been daunting to expatriate business executives. Other Chinese executives were also sentenced but none actually served time in prison.¹²⁰ The threat of criminal prosecutions and imprisonment, of course, creates intense fear among MNC corporate executives.

GSK is not alone in this high-profile crackdown on MNC pharmaceutical companies. China has singled out the pharmaceutical industry as a special target for its anti-corruption campaign.¹²¹ Other MNCs recently targeted on bribery charges

112. Yin Pumin, *Clamping Down on Corporation Bribery*, BEIJING REV. (Aug. 1, 2013), http://www.bjreview.com.cn/business/txt/2013-07/29/content_557941.htm.

113. See Bradsher & Buckley, *supra* note 99.

114. Joe McDonald, *Glaxo Case Shines Light on China's Medical Bribery*, AP NEWS ARCHIVE (Aug. 1, 2013, 12:12 AM), http://www.apnewsarchive.com/2013/Glaxo_case_shines_light_on_China%27s_medical_bribery/id-3f4efbb0b17f4385a2e6662655c38af5.

115. *Id.*

116. *Id.*

117. See Bradsher & Buckley, *supra* note 99.

118. See *id.*

119. See *id.*

120. See *id.*

121. See Pumin, *supra* note 112.

include Sanofi (France), Bayer (Germany), AstraZeneca (U.K.-Sweden), and Eli Lilly (United States).¹²² These MNCs feel unfairly targeted because they argue that Chinese drug companies have engaged in far more egregious conduct but have escaped prosecution.¹²³ MNCs believe that the real purpose of the anti-bribery crackdown is to force them to reduce their prices,¹²⁴ further discussed in the next section.

B. Price-Fixing under the Anti-Monopoly Law

China has also brought actions against MNCs under another competition law, the Anti-Monopoly Law (AML).¹²⁵ The AML encompasses many different aspects of anti-competitive behavior, such as abuse of power,¹²⁶ price fixing,¹²⁷ mergers and acquisitions that have anti-competitive effects,¹²⁸ and abuse of intellectual property rights.¹²⁹ A broader discussion of the problems that MNCs have faced under the various different provisions of the AML is beyond the scope of this Article; but one area that is directly related to the themes developed here is the use of the AML to impose fines on multinational pharmaceutical companies to pressure them to reduce their high prices.

One of the authorities charged with enforcement of the AML, the National Development and Reform Commission (NDRC), has aggressively pursued MNCs in the pharmaceutical sector for what the NDRC views as price fixing, *i.e.*, collusion by MNCs to set agreed upon prices for pharmaceuticals.¹³⁰ Indeed, “[i]n 2012, the NDRC investigated four drug classes comprising over 500 different

122. CESRC REPORT, *supra* note 2.

123. See Shobert, *supra* note 15.

124. See Neil Gough, *Western Companies Appear to Push Back Against Chinese Crackdown*, N.Y. TIMES (Sept. 3, 2014), <https://www.nytimes.com/2014/09/04/business/international/chinese-antitrust-investigations-alarm-western-companies.html>.

125. See Zhonghua Renmin Gongheguo Fan Longduan Fa (中华人民共和国反垄断法) [Anti-Monopoly Law of the People’s Republic of China] (promulgated by the 29th session of the Standing Comm. of the Tenth Nat’l People’s Cong., Aug. 30, 2007, effective Aug. 1, 2008).

126. See *id.* art. 3.2.

127. See *id.* art. 13.1.

128. See *id.* art. 3.3.

129. See *id.* art. 55.

130. See Simon Taylor, *Medtronic Fine Is a Warning Shot to Pharma, Medical Device Firms in China*, MLEX MARKET INSIGHT (Dec. 7, 2016), <https://mlexmarketinsight.com/insights-center/editors-picks/antitrust/asia/medtronic-fine>.

drugs, after which prices dropped by 17 percent.”¹³¹ The NDRC is known for its use of aggressive tactics, such as dawn raids, and the use of threats against MNCs.¹³² In one case, an NDRC official casually threatened MNCs with an investigation for asking a question at a conference.¹³³

One problem for MNCs is that the NDRC seems to have unchecked discretion to bring investigations.¹³⁴ An investigation alone is threatening because it is disruptive and because the NDRC’s power to fine is unchecked. The NDRC does not issue written explanations in making its decisions, so MNCs fear that NDRC decisions might be arbitrary.¹³⁵ While an appeal from an adverse NDRC decision is available in theory, MNCs are unlikely to appeal because of the fear of retribution by PRC authorities.¹³⁶ Rather than being subjected to intrusive and disruptive investigations, MNCs prefer to settle these cases by reaching an agreement with the NDRC to reduce their prices.¹³⁷

Some observers argue that these actions under the AUCL and AML are discriminatory and target MNCs over domestic companies who have engaged in similar or worse behavior.¹³⁸

131. CESRC REPORT, *supra* note 2, at 161.

132. See Michael Martina & Matthew Miller, ‘Mr. Confession’ and His Boss Drive China’s Antitrust Crusade, REUTERS (Sept. 15, 2014, 5:11 PM), <http://www.reuters.com/article/us-china-antitrust-ndrc-insight-idUSKBN0HA27X20140915>.

133. See Martina, *supra* note 12.

134. See THE US-CHINA BUS. COUNCIL, COMPETITION POLICY AND ENFORCEMENT IN CHINA 7 (2014), https://www.uschina.org/sites/default/files/AML%202014%20Report%20FINAL_0.pdf.

135. See Daniel C.K. Chow, *Rising Nationalism: China’s Regulation of Investment Trade*, in CHINA’S GLOBAL ENGAGEMENT: COOPERATION, COMPETITION, AND INFLUENCE IN THE 21ST CENTURY 67, 79 (Jacques deLisle & Avery Goldstein eds., 2017).

136. See U.S. CHAMBER OF COMMERCE, COMPETING INTERESTS IN CHINA’S COMPETITION LAW ENFORCEMENT 67-68 (Aug. 2014), https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf (“[F]irms are generally reluctant to appeal, either because NDRC’s determination is the outcome of an ‘agreement’ with the respondent, or because they fear retribution for appealing NDRC determinations given NDRC’s broad regulator powers over investment projects and the economy as a whole.”).

137. See Patrick Moorhead, *Qualcomm Settlement with China’s NDRC Removes Major Speedbump*, FORBES (Feb. 10, 2015, 9:26AM), <https://www.forbes.com/sites/patrickmoorhead/2015/02/10/qualcomm-settlement-with-chinas-ndrc-removes-major-speedbump/#153b9487431a>.

138. See Shobert, *supra* note 15.

MNCs also argue that real purpose of the bribery and competition law crackdown is to unfairly force them to reduce their prices.¹³⁹

IV. CHINA'S POLICIES IN THE AREA OF PATENTS AND TECHNOLOGY TRANSFER

China implements policies in the area of pharmaceuticals relating to patent and data exclusivity protections that are creating pressures on MNCs to provide access to their technologies. One of the most valuable assets of MNCs in China is their intellectual property (IP) assets and other protected proprietary information that might not qualify for IP protection. These assets include patents, trademarks, and clinical research data. MNCs claim that China is forcing them to transfer their technology to Chinese companies.¹⁴⁰ In this context, technology refers to valuable commercial knowledge protected by IP laws or by other means, such as periods of data exclusivity.¹⁴¹ The crux of the argument is that by providing inadequate protection of patents and clinical data for pharmaceuticals, China forces MNCs to make their technology available to the public domain sooner than would occur under a regime that provides a longer period of protection.¹⁴² As a consequence, China's current regime results in forced technology transfer.

A. China's Six-Year Data Exclusivity Protection

Drug manufacturers in the United States, China, and other countries must usually obtain regulatory approval for new drugs regardless of whether the drug is also protected by a patent.¹⁴³ If the patent can protect a new drug, most drug manufacturers obtain a patent as soon as possible to block competitors from filing for a patent for the same invention.¹⁴⁴ Only after the patent has been

139. See Gough, *supra* note 124.

140. See Wendy Wu, *Is China Making Life Difficult for Foreign Companies?*, S. CHINA MORNING POST (May 30, 2016, 5:11PM), <http://www.scmp.com/news/china/diplomacy-defence/article/1940397/china-making-life-difficult-foreign-companies>.

141. See *id.*

142. See *id.*

143. See Rongling Deng & Kenneth I. Kaitin, *The Regulation and Approval of New Drugs in China*, 37 DRUG INF. J. 29, 34 (2004).

144. See Ananya Mandal, *Drug Patents and Generic Pharmaceutical Drugs*, NEWS-MEDICAL.NET (Sept. 8, 2014), <http://www.news-medical.net/health/Drug-Patents-and-Generics.aspx>.

obtained will the MNC undergo the process of regulatory approval, which can take years.¹⁴⁵

Regulatory approval by the Food and Drug Administration in the United States (U.S. FDA) and the CFDA in China usually require testing of the new drug in clinical trials to ensure that the drug is safe and effective.¹⁴⁶ If the drug is protected by a patent, no competitors, such as generic drug manufacturers, can manufacture the patented drug until the patent expires.¹⁴⁷ Unlike the patented invention however, the clinical data used to obtain regulatory approval is not itself protected by IP laws, but by a different set of laws that provide protection in the form of data exclusivity.¹⁴⁸ These laws preclude other manufacturers from using the clinical data generated by the innovator drug company for a certain period of time, such as six years in the case of China.¹⁴⁹ To obtain regulatory approval to sell the generic drug by the FDA in the United States¹⁵⁰ and by the CFDA in China,¹⁵¹ the drug

145. See FDA, STEP 4: FDA REVIEW, <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405570.htm> (last visited April 26, 2017).

146. See, e.g., *id.*

147. See Mandal, *supra* note 144.

148. See Amy Zhou & David W. Cheng, *Following Pharmaceutical Data Protection in China*, MANAGING INTELL. PROP. (Mar. 1, 2014), <http://www.managingip.com/Article/3322867/Following-pharmaceutical-data-protection-in-China.html>.

149. *Id.*

150. *Abbreviated New Drug Application (ANDA)*, FOOD & DRUG ADMIN. (Nov. 28, 2017), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (“Generic drug applications are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is performs in the same manner as the innovator drug This demonstration of “bioequivalence” gives the rate of absorption, or bioavailability, of the generic drug, which can then be compared to that of the innovator drug.”) [hereinafter ANDA]; see Suzanne Dunne, Bill Shannon, Colum Dunne & Walter Cullen, *A Review of the Differences and Similarities Between Generic Drugs and Their Originator Counterparts, Including Economic Benefits Associated with Usage of Generic Medicines, Using Ireland as a Case Study*, 14 BMC PHARMACOLOGY AND TOXICOLOGY 1, 4 (2013), <https://bmcpharmacoltoxicol.biomedcentral.com/articles/10.1186/2050-6511-14-1>.

151. This abbreviated trial process is called “bioequivalence testing.” Steven J. Rizzi & Max Lin, *Generic Drug Approval Process in China* (July/Aug. 2011), https://www.foley.com/files/Publication/e29262fa-55dc-4d12-9c90-d2bb07794ba7/Presentation/PublicationAttachment/4f0dcc1f-bd20-4ee2-a9c6-d36f62a9adcc/RizziLin_DrugApproval.pdf (“Bioequivalence tests include human tests to determine if there is any statistical difference in absorption and absorption speed

manufacturer must conduct an abbreviated clinical trial of its generic drug. The abbreviated clinical trials used in generic drug testing require the generic drug manufacturer to demonstrate the bioequivalence of the generic drug to the patented drug.¹⁵² To show bioequivalence, the generic drug manufacturer must show, among other elements, that the generic drug is absorbed at the same rate of intensity and speed as the patented drug.¹⁵³ This requires the generic drug manufacturer to have access to data concerning the absorption intensity and speed of the patented drug generated in the patented drug's clinical trials.¹⁵⁴ The six-year data exclusivity in the patented drug's clinical data would delay the ability of the generic manufacturer to acquire the clinical information necessary to make the needed comparison to show bioequivalence and thus delay the regulatory approval of the generic drug. Thus, a delay in the approval of the generic drug means a delay in the entry of the generic drug into the marketplace where it can be sold.

Data exclusivity is required by Article 39.3 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),¹⁵⁵ one of the major treaties of the World Trade Organization (WTO) that all members, including the United States and China, must follow. In 2002, following the mandate of TRIPS Article 39.3, China enacted a six-year exclusivity period in the PRC Regulation for Implementation of Drug Administration

of the active component between the same or different dosage forms of the same drugs under the same test conditions, by using the methodology of a bioavailability study with pharmacokinetic parameters.”). Si-Yang Liu & Yi-Long Wu, *The Recent Reform of China's Drug Approval Process*, ASCO DAILY NEWS (May 26, 2016), <https://am.asco.org/recent-reform-chinas-drug-approval-process>.

152. See ANDA, *supra* note 150; see Rizzi & Lin, *supra* note 151.

153. See *id.*

154. See *id.*

155. Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 39, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994) (hereinafter TRIPS Agreement), stating in relevant part:

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair competition.”

Law.¹⁵⁶ Under Article 35 of the Drug Administration Law, the period of exclusivity is provided only for “new chemical entities,” a term borrowed from TRIPS Article 39.3 that is not otherwise defined in PRC law.¹⁵⁷ In 2007, Article 35 of the Drug Administration Law was further supplemented by Article 20 of the Provisions for Drug Registration, which reiterated the six-year period of data exclusivity.¹⁵⁸ Neither of these two laws further explains the meaning of “new chemical entities.”¹⁵⁹ As a result, China does not need to extend data exclusivity for drugs that do not constitute “new chemical entities” even though the drug might qualify as a new drug for the purposes of PRC patent law.¹⁶⁰ This disparity means that it would be possible for an MNC to obtain a patent for a drug in China using clinical data, but if PRC authorities were to find that the newly patented drug was not a new chemical entity, the MNC’s clinical data would be exposed to immediate use by any generic competitors.

Nothing in the TRIPS agreement of the WTO addresses this specific issue so China is free to set its own standards for which drugs constitute “new chemical entities” that qualify for the six-year period of data exclusivity.¹⁶¹ From an MNC’s perspective, this lack of oversight can lead to the belief that China can simply determine that a patented drug is not a “new chemical entity” and refuse to provide the six-year data exclusivity. Further, failure to define terms may mean that China is not extending data exclusivity protections to some MNCs. This could allow generic drug manufacturers, specifically Chinese companies supported or owned by the PRC government, access to clinical data immediately and allow them to enter the market sooner with competitive generic drugs.

156. See Yaopin Guanli Fa Shishi Tiaoli (药品管理法实施条例) [Regulations for the Implementation of the Drug Administration Law] (promulgated by the St. Council, Aug. 4, 2002, effective Sept. 15, 2002; rev’d Feb. 6, 2016), CLI.2.270932(EN) (Lawinfochina).

157. CARLOS MAREA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 16 (2002), http://www.who.int/medicines/areas/policy/protection_of_data.pdf.

158. See Yaopin Zhuze Guanli Banfa (药品注册管理办法) [Provisions for Drug Registration] (promulgated by the St. Food & Drug Admin., July 10, 2007, effective Oct. 1, 2007), art. 20, CLI.4.95037(EN) (Lawinfochina).

159. See Chen & Balzano, *supra* note 20, at 103.

160. See *id.*

161. See CORREA, *supra* note 157, at 16.

B. China's Requirement That Clinical Trials to be Conducted in China

MNCs based in the United States who seek patents and regulatory approval for their drugs in China usually have already obtained patents and regulatory approval in the United States. As part of the approval process in the United States, MNCs usually conduct clinical trials in the United States or overseas and submit data collected from those trials in order to obtain regulatory approval.¹⁶² MNCs who seek regulatory approval for their patented drugs in China are required by PRC laws to conduct their clinical trials in China.¹⁶³ Even though the MNCs might have already conducted clinical trials in the United States or in other countries as part of obtaining regulatory approval in the United States, none of this data can be used.¹⁶⁴ The MNC must conduct new trials in China even if this replicates work already done that was sufficient to satisfy the U.S. FDA.¹⁶⁵ This creates a serious disadvantage for MNCs. Both in terms of the unnecessary costs associated with duplicating worked already completed in the United States and in terms of the potentially reduced period of patent protection an MNC may receive.¹⁶⁶

Of course, MNCs face the issue of a shortened patent term due to the length of regulatory approvals not only in China but also in

162. See FDA, *supra* note 145.

163. See CERSC Report, *supra* note 2, at 165-66. Recently, however, Beijing has announced that it will allow the use of some drugs and medical devices based on approvals by foreign regulators. See *China to Allow Some Drugs Based on Foreign Approvals*, AP NEWS (Oct. 9, 2017), <https://apnews.com/8799fcff050c4fe4bc7533da0a1a7cd3/China-to-allow-some-drugs-based-on-foreign-approvals>. The announcement was vague on what types of foreign regulatory approvals would be recognized in China and further provided that there would be conditions attached. The announcement itself is too general and lacking in detail to indicate that China has definitely changed its position on clinical trials. This development is worth monitoring to see the details that emerge and the eventual laws and regulations, if any, which are passed to see whether they will permit the use of foreign clinical trials for drug approvals and under what conditions for regulatory approval in China.

164. See Yaopin Zhuze Guanli Banfa (药品注册管理办法) [Provisions for Drug Registration] (promulgated by the St. Food & Drug Admin., July 10, 2007, effective Oct. 1, 2007), art. 30, CLI.4.95037(EN) (Lawinfochina).

165. See *id.*

166. As noted above, since the MNC will obtain a Chinese patent as soon as possible for its drug in China, the clinical trial will occur only after the patent has been obtained. Since the term of patent protection in China is 20 years (as required by TRIPS) from the date of the filing of the patent, the length of the clinical trial period, including any delays, would effectively reduce the period of patent protection.

the United States and other countries as well. The same process is followed in the United States; the MNC first obtains the patent to avoid losing the patent to a competitor and then undergoes the process of regulatory approval, which is also a multi-year process.¹⁶⁷ Both the United States and the European Union, another major drug market, however, extend marketing exclusivity at the back end of the patent to compensate for extended clinical trial approvals; in this context, marketing exclusivity refers to the exclusive right of the MNC to sell the drug.¹⁶⁸ In the United States, MNCs are given periods of marketing exclusivity of 180 days, six months, or three, five, or seven years, depending on the case.¹⁶⁹ The period of exclusivity runs from the date of approval of the drug and can be concurrent with the patent term or can extend beyond the patent term if the period of approval is particularly lengthy.¹⁷⁰ Although marketing exclusivity is not technically an extension of the patent term (marketing exclusivity and patent term protection are distinct legal concepts), the effect of the U.S. and E.U. grant of marketing exclusivity is to give the patent owner the equivalent of an extension of the monopoly period to commercially exploit the patent.¹⁷¹ In China, however, there is no extension of marketing exclusivity at the back end of the patent to compensate for the time lost on the patent in obtaining regulatory approval.¹⁷² Since MNCs are the owners of the most commercially valuable drug patents in China, MNCs are disadvantaged because it shortens the time period in which they can commercially exploit

167. See Gail A. Van Norman, *Drugs and Devices: Comparison of European and U.S. Approval Processes*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 399, 402 (2016).

168. See RENU LAL, FDA, PATENTS AND EXCLUSIVITY 1 (May 19, 2015), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf>; see also CAROLYNE HATHAWAY ET AL., LATHAM & WATKINS, EXCLUSIVITY STRATEGIES IN THE UNITED STATES AND EUROPEAN UNION 34, 36-38 (May/June 2009), https://www.lw.com/upload/pubcontent/_pdf/pub2655_1.pdf (discussing EU market exclusivity).

169. For a discussion of these periods by the FDA, see LAL, *supra* note 168, at 1-3.

170. See *id.*

171. See *id.*

172. See Gabin Recchia & Joanna Jones, *Pharmaceutical Patent Term Extension and Data Exclusivity in Australia, New Zealand, and Asia: Are You Missing Out?*, LEXOLOGY (June 5, 2015), <http://www.lexology.com/library/detail.aspx?g=a78d9972-70b3-4707-9e4f-94192c6c21cb>.

their patents.¹⁷³ This policy can be viewed as a form of forced technology transfer because the requirement of having to conduct clinical trials in China and the lack of a compensating extended marketing exclusivity right in China effectively shortens the period under which the patent can be commercially exploited.¹⁷⁴ After the shortened patent period expires, the patented drug becomes part of the public domain, free for state-owned or state-sponsored Chinese companies in the generic drug industry to copy and exploit.

From China's perspective, requiring the clinical trials to be conducted in China provides a number of advantages. MNCs are required to conduct research and development (R&D) in China, which includes the preparation and supervision of the clinical trials; the trials can involve extra costs due to the legal requirement that the trials use constantly changing medical records of Chinese patients;¹⁷⁵ thus MNCs may need to perform additional work necessary to prepare the clinical data involving Chinese patients for regulatory approval. This will involve additional investment by MNCs in the form of capital and labor. For example, in 2011, Merck announced it will be spending \$1.5 billion to enhance its R&D capacity in China.¹⁷⁶ In addition, the data collected from the clinical trials may be subject to theft or misuse by competitors in China.¹⁷⁷

173. MNCs are effectively given a twelve-year patent monopoly instead of the minimum twenty-year period required by TRIPS.

174. The combination of having to conduct clinical trials in China and the lack of a compensating exclusive right at the end of the patent causes the effective length of the patent term to twelve years or about sixty percent of the minimum twenty-year term required by TRIPS. See Don Durfee, *Update 2-Merk & Co to Invest \$1.5 Bln for R&D in China*, REUTERS (Dec. 6, 2011, 6:46 AM), <http://www.reuters.com/article/merck-idUSL3E7N64HA20111206>.

175. See Moe Alsumdaie, *Challenges with Running Clinical Research in China*, APPLIED CLINICAL TRIALS ONLINE (Oct. 6, 2016), <http://www.appliedclinicaltrials.com/running-clinical-research-china> (discussing the problems with using clinical data in China caused by the requirement in China that drug companies must include Chinese patients as part of the clinical trial of the drug needed for regulatory approval and how medical records in Chinese state hospitals are constantly being amended).

176. See Durfee, *supra* note 176.

177. The theft of trade secrets has emerged as a serious business problem for MNCs in China. See generally Daniel C.K. Chow, *Navigating the Minefield of Trade Secrets Protection in China*, 47 VAND. J. TRANSNAT'L L. 1007, 1008-09 (2014) (describing two recent cases of suspected trade secret appropriation).

C. China's Compulsory Licensing Provision

In 2012, the PRC State Intellectual Property Office (SIPO) issued a new revision of its compulsory license rules that apply to all patents.¹⁷⁸ Article 5 of the rules states that a party can apply to the patent authorities for a compulsory license if “the patentee fails to give good reason for failing to fully or sufficiently implement the patent right three years from the date of the patent being granted, and that it has been four years from the date of applying for the patent.”¹⁷⁹ The rules do not further define “good reason.” Article 73 of the Implementing Regulations of the Patent Law defines “failing to fully or sufficient implement” as “the method or scale of implementing patent [that] does not satisfy China’s patent products or patent process requirements.”¹⁸⁰

As these rules indicate, a “compulsory” license is not a license, but a right granted by PRC patent authorities to a third party to use the patent without the consent of the patent owner and usually contrary to the direct wishes of the patent owner.¹⁸¹ This allows a Chinese pharmaceutical company to apply to SIPO or its local branches for a compulsory license that would force an MNC to license its patent to the Chinese company so long as the Chinese patent authorities find that the conditions for a compulsory license are satisfied.¹⁸² As the text of the rules set forth above indicates, the standards are vague enough to allow the PRC patent authorities wide discretion in deciding whether to grant compulsory licenses for pharmaceutical patents.

Compulsory licenses are authorized by Article 31 of TRIPS,¹⁸³ and the term is given an expansive and flexible interpretation by sections of the 2001 Doha Ministerial Declaration relating to

178. See Zhuanli Shishi Qiangzhi Xuke Banfa (专利实施强制许可办法) [Measures for Compulsory License for Patent Exploitation] (promulgated by Order No. 64 by the State Intellectual Property Office on Mar. 12, 2012, effective May 1, 2012).

179. See *id.* art. 5.

180. See Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize (中华人民共和国专利法实施细则) [The People's Republic of China Patent Law Implementing Rules] (promulgated by Order No. 306 of the State Intellectual Property Office on June 15, 2001, amended on Dec. 8, 2002, Jan. 9, 2010 and effective as of Feb. 1, 2010).

181. Tony Chen & Luckie Hong, *China's Compulsory Licenses – A Danger to Pharma Patents*, LAW360 (Oct. 1, 2012, 1:26 PM), <https://www.law360.com/articles/381731/china-s-compulsory-licenses-a-danger-to-pharma-patents>.

182. See *id.*

183. See TRIPS Agreement, *supra* note 155, art. 31.

TRIPS.¹⁸⁴ The purpose of the Doha Declaration was to give developing countries a broader power to issue compulsory licenses so that they can obtain greater access to medicines, which might otherwise be unaffordable for these countries due to the monopoly power to fix high prices conferred by the patent rights to the medicines owned by MNCs.¹⁸⁵ The Doha Declaration was issued as a result of an intense international debate over access to medicines and represents a victory for developing countries.¹⁸⁶ The history of the developments behind the compulsory license in the WTO suggest that China's new compulsory license rules might be consistent with the WTO and might be able to withstand a WTO challenge.

In 2012, India issued a compulsory license to a generic drug manufacturing company, Natco Pharma, for a Bayer patent protecting Bayer's cancer treatment drug, Nexavar.¹⁸⁷ Natco offered to sell the generic version at \$175, a ninety-seven percent reduction over the cost of Bayer's drug.¹⁸⁸ So far, China has not issued a compulsory license for a pharmaceutical patent, but this does not mean that the compulsory licensing law is not effectively creating new pressures on MNCs.¹⁸⁹ The India Natco case is a rare case in which a country issued a compulsory license; when confronted with the possibility of a country issuing a compulsory license, most MNCs would rather reduce their prices than be forced into a compulsory licensing arrangement.¹⁹⁰ A compulsory license is highly disadvantageous to MNCs because they are forced to allow an unrelated third party access to the MNC's proprietary technology. Such access would allow a third party to abuse the

184. See World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/MIN(01)/DEC/2, 41 ILM 775 (2002) [hereinafter Doha Declaration] (explicitly giving member countries freedom to determine the ground upon which compulsory licenses are granted); World Trade Organization, General Council Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 43 ILM 509,(2004) [hereinafter Paragraph 6 Declaration].

185. See Doha Declaration, *supra* note 184; see also Paragraph 6 Declaration, *supra* note 184.

186. See Correa, *supra* note 157.

187. See Chen & Hong, *supra* note 181.

188. See *id.*

189. See Tan Ee Lyn, *China changes Patent Law in fight for Cheaper Drugs*, REUTERS (June 8, 2012, 10:44AM), <http://www.reuters.com/article/us-china-medicines-patents-idUSBRE8570TY20120608>.

190. See, e.g. *id.* After China adopted its compulsory license program Gilead offered China concessions regarding its anti-HIV drug tenofovir.

technology once it obtained access.¹⁹¹ In voluntary licensing situations, the MNC can conduct due diligence to determine whether the potential licensee can be trusted with its technology; none of this is possible in a compulsory license situation as the MNC is forced to give access to its technology to an unrelated party from which the MNC receives no assurances of honesty or fair dealing.

The threat to issue a compulsory license, as opposed to actually issuing the license, serves as a means to pressure MNCs to reduce prices.¹⁹² In this light, China's issuance of the new rules can be viewed as creating new tools for China to force MNCs to lower their prices. The issuance of the compulsory licensing rules by itself might not be viewed as an ominous development, but taken together with the other developments discussed in this Article, the new rules can be seen as part of an overall strategy by China to force MNCs to lower their prices for drugs in China and to force technology transfers to Chinese companies.

V. CHINA'S RISING NATIONALISM AND PROTECTIONISM

The problems facing MNCs in the pharmaceutical sector might seem to be disparate and unrelated. But, these problems can be traced to a common source: China's rising nationalism and protectionism, manifesting in policies favoring local companies and interests at the expense of foreign competition and nations.¹⁹³ In the area of counterfeiting and substandard ingredients, this protectionism is manifested in the refusal of PRC authorities to cooperate with foreign governments in the punishment of counterfeiters. In the cases of contaminated heparin and poisoned glycol, PRC authorities refused to disclose the names and locations of counterfeiters even though all evidence indicated that the PRC

191. The third party might misuse the technology or misappropriate it. For this reason, patent owners will carefully screen potential licensees for trustworthiness. A compulsory license imposes a licensee on the patent owner who has no choice but to accept the licensee. Most patent owners find this to be a highly unfavorable arrangement and would rather submit to a reduction in price instead of a compulsory license. See DANIEL C.K. CHOW & EDWARD LEE, *INTERNATIONAL INTELLECTUAL PROPERTY: PROBLEMS, CASES, AND MATERIALS* 480-81 (3d ed. 2017).

192. See Lyn, *supra* note 189.

193. A more detailed analysis of these policies is beyond the scope of this Article. See Daniel C.K. Chow, *How China Promotes Its State-Owned Enterprises at the Expense of Multi-National Companies Doing Business in China and in Other Countries*, 41 N.C.J. INT'L L. 455 (2016) for a more detailed discussion of these policies.

authorities had this information within their grasp. It was more important to the authorities to protect counterfeiters who benefit the local economy by generating export sales and revenue than to enforce the rights of overseas victims of the harmful exports. In the case of the crackdown on MNCs for bribery and other competition law-related violations, the PRC authorities are using tactics designed to pressure, harass, and intimidate MNCs into lowering their prices for their products. Lower prices benefit Chinese consumers as well as domestic competitors of MNCs in their respective product categories. Economic benefits redound to Chinese consumers in the form of lower prices and to domestic competitors in the form of more favorable competitive conditions at the expense of MNCs. In the area of technology transfer, PRC authorities use policies that force MNCs to transfer their technology to local competitors. China does so by imposing requirements that effectively shorten or limit protections for proprietary technology owned by MNCs. These limitations on protection result in the proprietary technology entering the public domain sooner where it then becomes available to local PRC companies to use in making their own products.

China's rising nationalism and protectionism raise serious concerns for the United States and the rest of the world.¹⁹⁴ These issues go beyond the typical business problem faced by MNCs and relate to underlying geo-political and economic issues between China and the United States. The nature of these problems suggests that there are no neat short-term solutions but that a long-term approach is required.

VI. CONCLUSION

In considering what measures MNCs can take to deal with the problems examined in this study, we can begin by emphasizing that technical measures, such as the popular enforcement-based approaches in the area of counterfeiting, will be inadequate to address the problem.¹⁹⁵ An enforcement-based approach is one that focuses exclusively or primarily on seizing illegal product, imposing fees, capturing suspects, and criminal prosecution. The discussion of counterfeiting and sale of substandard APIs indicates

194. See Daniel C.K. Chow, *Anti-Counterfeiting Strategies of Multi-National Companies in China: How a Flawed Approach is Making Counterfeiting Worse*, 41 GEO J. INT'L L. 749, 750-52 (2010) for further discussion.

195. See *id.* (discussing enforcement-based approaches in China to deal with counterfeiting).

that PRC authorities have refused to disclose the location of counterfeit factories, knowledge that was fully within their control, due to various political reasons. It should be apparent that no amount of enforcement can stem the outflow of counterfeit and substandard product so long as the existing government authorities refuse to cooperate with foreign companies and governments in enforcement.

Similarly, in the area of bribery and competition law, no amount of prophylactic measures within the MNC and no amount of cracking down by the MNC on the giving of bribes by its employees will be effective to stem the harsh treatment of MNCs if the PRC government believes at a basic level that prices for drugs are too high and is intent on forcing MNC pharmaceutical companies to lower their prices to make the products more available to consumers. In the area of technology transfer, no amount of corporate security measures to prevent the theft of valuable technology by competitors will be effective if the PRC government has an underlying policy of promoting domestic PRC generic drug companies at the expense of MNC pharmaceutical companies. In all of these areas, technical measures, such as enforcement, training programs to prevent bribery, and security measures to protect technology will not address the underlying concern that the PRC government has political and bureaucratic motives that lead to these problems.

The analysis in this Article suggests that a more fertile approach would be one that focuses on long-term legal and political reform, combined with short-term technical measures. This might cause the PRC government to reexamine the root causes of why PRC government entities refuse to identify the location of a counterfeiter to foreign authorities. This approach more directly addresses the root causes of the counterfeiting and substandard products problem.

An examination of the policy of the PRC government to promote domestic drug companies at the expense of MNCs in the pharmaceutical area would be more direct and effective than attempting to argue for a technical interpretation of China's data exclusivity laws that will permit MNCs to protect their data. Even if such a technical approach is successful, The PRC government will find other ways to benefit domestic drug companies at the expense of MNCs. In other words, any approach must be a long-term approach that focuses on legal and political reform; this is the only way to address these issues at a fundamental level. Of course, MNCs today take a short-term view and want immediate results,

not changes that could take years or even decades. While this desire is understandable and appears to be part of the current corporate culture, MNCs must take a long-term, patient approach in dealing with China. Only by being patient and seeking to address the underlying root causes of common business problems in China can MNCs make meaningful progress in improving the PRC's business environment.