China's Innovative Turn and the Changing Pharmaceutical Landscape

Peter K. Yu*

I. INTRODUCTION

For more than a decade, China has been the world's leading supplier of active pharmaceutical ingredients ("APIs").[1] Today, it is not only the world's

 Professor of Law, Professor of Communication, and Director, Center for Law and Intellectual Property, Texas A&M University. Earlier versions of this Article were presented at the "Changing Regulation of Pharmaceuticals: Pricing, Intellectual Property, Trade and Ethics" Symposium at the University of the Pacific McGeorge School of Law, as a keynote address at the 11th Conference of the United States–China Intellectual Property Institute hosted by the Faculty of Law of the Chinese University of Hong Kong, and at the Webinar on "China's Changing Role in the Global Pharmaceutical System: Implications for National and Global Public Health" organized by the Global Health Centre at the Graduate Institute of Geneva. The Author is grateful to Albert Wai-Kit Chan, Christopher Holman, Lee Jyh-an, Michael Mireles, and Suerie Moon for their kind invitations and Frederick Abbott and other event participants for their valuable comments and suggestions.

1. *See* Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 363 (2008) [hereinafter Yu, *Access to Medicines*] ("[China] already is the world's largest producer of active pharmaceutical ingredients and is likely to be a very important player in the generic market."); *see also* WORLD HEALTH ORG. [WHO], CHINA POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 17 (2017), https://www.who.int/phi/publications/2081China020517.pdf [hereinafter WHO CHINA STUDY] (on file with *The University of the Pacific Law Review*) (prepared by Frederick Abbott) ("China is the world's leading producer and exporter of [APIs] by volume, accounting for 20% of total global API output. China produces over 2000 API drug products, with annual production capacity exceeding 2 million tons." (footnote omitted)). *See generally id*. at 17–18 (discussing China's production and export of APIs).

second largest pharmaceutical market, behind only the United States,[2] but it also produces about four percent of the world's new pharmaceutical products.[3] Despite these impressive accomplishments, China does not have internationally recognized pharmaceutical brands that are comparable to those found in Europe or the United States, such as Johnson & Johnson, Merck, Novartis, Pfizer, Roche, and Sanofi.[4] Nor does China rival India in its status as the "pharmacy of the world,"[5] providing generic drugs to needy countries from around the world,[6] especially those in sub-Saharan Africa.[7]

Since the mid-2000s, China has taken an innovative turn that has serious ramifications for the global pharmaceutical landscape and future developments at the intersection of intellectual property and public health. To be sure, many policymakers and commentators still focus unduly on the problems in the Chinese intellectual property system.[8] Notable examples from the past few years

---

2. *See* Issaku Harada, *China Extends Drug Patents to 25 Years*, NIKKEI ASIAN REV. (May 16, 2018), https://asia.nikkei.com/Politics/China-extends-drug-patents-to-25-years (on file with *The University of the Pacific Law Review*) ("China's pharmaceutical market is now worth more than $120 billion, second only to America's.").

3. *See* CHINA PHARM. ENTERS. ASS'N ET AL., FOSTERING A SUSTAINABLE ECOSYSTEM FOR DRUG INNOVATION IN CHINA 3 (2016), http://enadmin.rdpac.org/upload/upload_file/1577873373.pdf (on file with *The University of the Pacific Law Review*) ("Measured by the number of pipeline drugs and new drugs launched, China is in the third tier, contributing around 4% to global drug innovations, lagging far behind the first tier[,] the US (~50%)[,] and countries in the second tier such as the UK and Japan."); Ma Huateng, Tencent, *Application of Artificial Intelligence and Big Data in China's Healthcare Services*, *in* GLOBAL INNOVATION INDEX 2019: CREATING HEALTHY LIVES—THE FUTURE OF MEDICAL INNOVATION 103, 108 (Soumitra Dutta et al. eds., 2019) [hereinafter GLOBAL INNOVATION INDEX 2019] ("China has independently researched and developed new drugs in recent years that have contributed about 4% to the global novel drug market, approximately one-twelfth of the contribution from that of the United States of America.").

4. *See* Michael Christel, *Pharm Exec's Top 50 Companies 2019*, PHARMACEUTICAL EXECUTIVE (July 12, 2019), http://www.pharmexec.com/pharm-execs-top-50-companies-2019 (on file with *The University of the Pacific Law Review*) (listing the top 50 global biopharma players in 2019 based on drug sales); *The Top Ten Pharmaceutical Companies by Market Share in 2018*, PHARMACEUTICAL TECH. (Mar. 7, 2019), https://www.pharmaceutical-technology.com/features/top-pharmaceutical-companies/ (on file with *The University of the Pacific Law Review*) (listing the top ten pharmaceutical companies in 2018 based on market share).

5. *See* Shamnad Basheer & Pankhuri Agarwal, *India's New IP Policy: A Bare Act?*, 13 INDIAN J.L. & TECH. 1, 22 (2017) (noting that the Indian pharmaceutical industry has earned the moniker "pharmacy of the world").

6. *See* KAMAL NATH, INDIA'S CENTURY 110 (2008) (noting that India "makes more than a fifth of the world's generic drugs"); Kenneth C. Shadlen, *Is AIDS Treatment Sustainable?*, *in* THE GLOBAL GOVERNANCE OF HIV/AIDS: INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES 29, 36 (Obijiofor Aginam, John Harrington & Peter K. Yu eds., 2013) ("It is estimated that more than half of those receiving AIDS treatment in the developing world are treated with generic [antiretrovirals] produced in India.").

7. *See* Colleen V. Chien, *HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?*, 2 PLOS ONE e278, 2 (2007) (stating that India provided eighty-five percent of generic HIV/AIDS antiretrovirals in Sub-Saharan Africa).

8. For the Author's earlier discussions of the piracy and counterfeiting problems in China, *see generally* Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle*, *in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 173 (Daniel J. Gervais ed., 1st ed. 2007); Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U. L. REV. 131 (2000) [hereinafter Yu, *From Pirates to Partners I*]; Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in Post-WTO*

included the Trump administration's Section 301 reports[9] and the United States' second complaint against China[10] for violating the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of the World Trade Organization ("WTO").[11] Nevertheless, it is time that policymakers and commentators paid greater attention to the changing Chinese pharmaceutical landscape and its many ramifications.

Part II recounts China's innovative turn, tracing the developments back to the mid-2000s when Chinese leaders began to make a major policy push toward the development of independent innovation. Part III examines the changing pharmaceutical landscape in China, drawing illustrations from the recently proposed amendments to Chinese patent law and pharmaceutical regulations. Part IV explores the ramifications of China's increasing assertiveness in the pharmaceutical arena, at both the domestic and global levels. Specifically, this Part discusses three sets of ramifications: the changing discourse on intellectual property developments in China, the internal challenges that confront the country at this time of policy transition, and the global complications that will affect the future development of the international trading and intellectual property systems.

II. CHINA'S INNOVATIVE TURN

Although China has a longstanding history of innovation,[12] including medical

China, 55 AM. U. L. REV. 901 (2006) [hereinafter Yu, *From Pirates to Partners II*]; Peter K. Yu, *The Middle Kingdom and the Intellectual Property World*, 13 OR. REV. INT'L L. 209 (2011).

9. *See* OFFICE OF THE U.S. TRADE REPRESENTATIVE, FINDINGS OF THE INVESTIGATION INTO CHINA'S ACTS, POLICIES, AND PRACTICES RELATED TO TECHNOLOGY TRANSFER, INTELLECTUAL PROPERTY, AND INNOVATION UNDER SECTION 301 OF THE TRADE ACT OF 1974 (2018) [hereinafter SECTION 301 INVESTIGATION REPORT] (providing the final report of the investigation); OFFICE OF THE U.S. TRADE REPRESENTATIVE, UPDATE CONCERNING CHINA'S ACTS, POLICIES AND PRACTICES RELATED TO TECHNOLOGY TRANSFER, INTELLECTUAL PROPERTY, AND INNOVATION (2018) (providing an update to the earlier report).

10. *See* Request for Consultations by the United States, *China—Certain Measures Concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS542/1 (Mar. 23, 2018) [hereinafter *Second TRIPS Complaint*] (providing the complaint). Although the WTO Dispute Settlement Body established a panel in November 2018, it has since suspended the panel proceedings at the United States' request. *See China—Certain Measures Concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS542/10 (June 14, 2019) (requesting the suspension of the WTO panel proceedings). The first complaint the United States filed against China is *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*. Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WTO Doc. WT/DS362/R (adopted Jan. 26, 2009); *see also* Peter K. Yu, *The TRIPS Enforcement Dispute*, 89 NEB. L. REV. 1046 (2011) (discussing this dispute); Peter K. Yu, *TRIPS Enforcement and Developing Countries*, 26 AM. U. INT'L L. REV. 727 (2011) (same).

11. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

12. For discussions of scientific developments in China, see generally BENJAMIN A. ELMAN, ON THEIR OWN TERMS: SCIENCE IN CHINA, 1550–1900 (2005); JOSEPH NEEDHAM, SCIENCE AND CIVILISATION IN CHINA (1956–2004); ROBERT TEMPLE, THE GENIUS OF CHINA: 3,000 YEARS OF SCIENCE, DISCOVERY & INVENTION (2007).

innovations[13]—and it adopted a patent law in 1912[14] and another in 1944[15]—it did not establish a modern patent system until its economy reopened to the outside world in the late 1970s.[16] In 1984, China established the Patent Law, reviving the protection that inventions had once enjoyed.[17] Except for a brief period from 1950 to 1954, during which patents were granted in the then-newly founded People's Republic of China, inventors obtained protection through inventors' certificates (*faming zhengshu*) and other types of awards or remuneration.[18] A few months after the adoption of the 1984 Patent Law, China acceded to the Paris Convention for the Protection of Industrial Property,[19] which took effect in the country on March 19, 1985.[20]

---

13. As one commentator observed:

> *The Yellow Emperor's Classic* provides the first recorded evidence of widespread use of [traditional Chinese medicine] in mainland China. This ancient text, written prior to 85 B.C., details traditional methods of diagnosis and treatment. Later written examples of traditional diagnosis and healing testify to China's rich medical history, as well as to some correlation between the basic theories and products used for treatment.

Teresa Schroeder, Comment, *Chinese Regulation of Traditional Chinese Medicine in the Modern World: Can the Chinese Effectively Profit from One of Their Most Valuable Cultural Resources*, 11 PAC. RIM L. & POL'Y J. 687, 689 (2002) (footnotes omitted).

14. *See* Peter K. Yu, *Building the Ladder: Three Decades of Development of the Chinese Patent System*, 5 WIPO J. 1, 4 (2013) [hereinafter Yu, *Building the Ladder*] ("China introduced a substantive patent law in 1912, the year after the fall of the last imperial dynasty in China. Titled the Provisional Regulations on Awards for Devices (Creations), the law offered foreign patent owners very limited protection despite what it stated on paper.").

15. *See id*. ("Although a new patent law was finally introduced in 1944, shortly before the end of the Second World War, the patent system never took off in mainland China following Guomindang's retreat to Taiwan. That system eventually became the Taiwanese patent system.").

16. *See generally* IMMANUEL C.Y. HSÜ, THE RISE OF MODERN CHINA 858–69 (6th ed. 2000) (discussing China's adoption of the Open-Door Policy in December 1978, which provided "a complete reversal of the Maoist policy of seclusion that had been in force . . . between 1958 and 1978").

17. Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, effective Apr. 1, 1985) (China) [hereinafter 1984 Patent Law].

18. Immediately after the founding of the People's Republic of China in 1949, patent protection was retained in the Provisional Regulations Governing Invention and Patent Rights, which was adopted in 1950 and also covered inventors' certificates. Pursuant to these regulations, the first Chinese patent issued to the inventor of a soda-making process. ZHENG CHENGSI WITH MICHAEL D. PENDLETON, CHINESE INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER LAW 52 (1987). Nevertheless, patents were quickly phased out, and emphasis had shifted toward other types of awards or remuneration in the next three decades:

> [The 1950] regulations were quickly modified in 1954 with the enactment of the Provisional Regulations Concerning Awards for Inventions with Regard to Products, Technical Improvements and Rationalisation Proposals. Between 1950 and 1963, "only four patents and six inventor certificates were granted". In December 1963, the regulations were once again replaced by the Regulations Concerning Awards for Inventions and the Regulations Concerning Awards for Technical Improvement Proposals. Many of these regulations were direct transplants from the Soviet Union.

Yu, *Building the Ladder*, *supra* note 14, at 5 (footnotes omitted).

19. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1538, 828 U.N.T.S. 305 (revised at Stockholm July 14, 1967).

20. World Intellectual Prop. Org. [WIPO], *WIPO-Administered Treaties: Contracting Parties > Paris Convention*, https://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last visited Aug. 5, 2019) (on file with *The University of the Pacific Law Review*).

Although the 1984 statute ushered in a new innovation system, its effectiveness "was greatly limited by a lack of experience with patent protection, the uneasiness about introducing private rights in a socialist environment and a myriad of compromises struck in the drafting process."[21] Notably, Article 25 excluded "pharmaceutical products, and substances obtained by means of a chemical process,"[22] similar to the exclusions found in the patent laws of India and other developing countries.[23] Such limited protection in the patent area, as well as in other areas of intellectual property law such as copyright,[24] eventually led to increased external pressure from the United States and other developed countries.[25]

In January 1992, China signed the Memorandum of Understanding on the Protection of Intellectual Property with the United States, agreeing to strengthen the protections for pharmaceuticals.[26] Article 1(a) stated explicitly that "[p]atents shall be available for all chemical inventions, including pharmaceuticals and agricultural chemicals, whether products or processes."[27] Article 2 further noted China's "agree[ment] to provide administrative protection to U.S. pharmaceutical and agricultural chemical product inventions."[28]

Pursuant to this memorandum of understanding, China amended its patent law in September 1992,[29] expanding the scope of protection to cover foods, beverages, condiments, pharmaceutical products, and "substances obtained by means of a chemical process."[30] In addition, the amended law added the right to

---

21. Yu, *Building the Ladder*, *supra* note 14, at 7. For discussions of the debates surrounding the drafting of the 1984 Patent Law, see generally WILLIAM P. ALFORD, TO STEAL A BOOK IS AN ELEGANT OFFENSE: INTELLECTUAL PROPERTY LAW IN CHINESE CIVILIZATION 66, 70 (1995); ANDREW C. MERTHA, THE POLITICS OF PIRACY: INTELLECTUAL PROPERTY IN CONTEMPORARY CHINA 82–87 (2005); Yu, *Building the Ladder*, *supra* note 14, at 6.

22. 1984 Patent Law, *supra* note 17, art. 25(5).

23. *See* Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1632–33 (2013) [hereinafter Yu, *Virotech Patents*] (discussing the Tek Chand Committee, the Ayyangar Committee, and the 1970 Patent Act in India, which denied patent protection to pharmaceutical products).

24. *See* Yu, *Building the Ladder*, *supra* note 14, at 8 (noting that, in the mid-1980s, "the United States' main intellectual property concern was copyrights, not patents").

25. *See* Warren H. Maruyama, *U.S.–China IPR Negotiations: Trade, Intellectual Property, and the Rule of Law in a Global Economy*, *in* CHINESE INTELLECTUAL PROPERTY LAW AND PRACTICE 165, 186 (Mark A. Cohen et al. eds., 1999) ("At a 1985 meeting to the U.S.–China Joint Committee on Commerce and Trade (JCCT), the U.S. for the first time expressed concerns about weak Chinese IPR [intellectual property right] standards. In 1987, the U.S. put IPR protection on the agenda for U.S.–China market access talks."); *see also* Yu, *From Pirates to Partners I*, *supra* note 8, at 140–51 (describing the United States' use of section 301 sanctions and various trade threats to induce China to strengthen protections for intellectual property rights).

26. Memorandum of Understanding Between the Government of the United States of America and the Government of the People's Republic of China on the Protection of Intellectual Property, China–U.S., Jan. 17, 1992, T.I.A.S. No. 12036 (1995).

27. *Id*. art. 1(a).

28. *Id*. art. 2.

29. Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Sept. 4, 1992, effective January 1, 1993) (China) [hereinafter 1992 Patent Law].

30. *Compare* 1984 Patent Law, *supra* note 17, art. 25(4) (denying patent protection to "foods, beverages and condiments"); *id*. art. 25(5) (denying patent protection to "pharmaceutical products, and substances

import,[31] extended patent protection to both products and processes,[32] and lengthened the duration of protection from fifteen to twenty years.[33] The law also severely curtailed the scope of compulsory licenses, which were of great concern to the U.S. pharmaceutical industry.[34] Taken together, these amended provisions introduced to China the high patent standards that were then under negotiation at the Uruguay Round of Multilateral Trade Negotiations and that would soon find their way to the final text of the TRIPS Agreement.[35] A year after the adoption of the 1992 Patent Law, China joined the Patent Cooperation Treaty ("PCT").[36]

In the next few years, China prepared to join the WTO and worked hard to conform its intellectual property laws to the TRIPS requirements.[37] In August 2000, China amended its patent law for the second time.[38] Consistent with the TRIPS Agreement, the law prohibited the "offers for sale" of infringing products,[39] tightened the standards for obtaining a compulsory license,[40] and allowed for the judicial review of patent invalidations.[41] To strengthen protections for both local and foreign rights holders, the law required innocent infringers to prove the legitimate source of the patented product.[42] When it was difficult to determine damages, the amended law allowed for calculation based on appropriate royalties.[43] In December 2001, China finally became the 143rd member of the WTO.[44]

---

obtained by means of a chemical process"), *with* 1992 Patent Law, *supra* note 29, art. 25 (omitting these two categories from patent ineligibility).

31. 1992 Patent Law, *supra* note 29, art. 11.

32. *Id*.

33. *Id*. art. 45.

34. *Compare* 1984 Patent Law, *supra* note 17, arts. 51–58 (providing for compulsory licenses), *with* 1992 Patent Law, *supra* note 29, arts. 51–58 (providing new arrangements for compulsory licenses).

35. *See* TRIPS Agreement, *supra* note 11, art. 27.1 (requiring WTO members to offer patent protection to "any inventions, *whether products or processes*, in all fields of technology" (emphasis added)); *id*. art. 28.1 (covering "importing" in addition to the "making, using, offering for sale, [or] selling" of patented products); *id*. art. 31 (allowing for use without the patent holder's authorization); *id*. art. 33 ("The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.").

36. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231. The PCT took effect in China on January 1, 1994. Since 1994, the Chinese Patent Office, and later SIPO and then the CNIPA, has served as an international searching authority for PCT purposes. PETER DRAHOS, THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS 233 (2010).

37. *See* Yu, *Building the Ladder*, *supra* note 14, at 10 ("[T]he Second Amendment was adopted to conform the Chinese patent system to WTO standards. The need for such conformity was understandable considering China's willingness to make significant sacrifices to join the WTO.").

38. Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Aug. 25, 2000, effective July 1, 2001) (China).

39. *Id*. art. 11.

40. *Id*. arts. 48–50.

41. *Id*. art. 46.

42. *Id*. art. 63.

43. *Id*. art. 60.

44. *See* Press Release, World Trade Org., WTO Ministerial Conference Approves China's Accession (Nov. 11, 2001), https://www.wto.org/english/news_e/pres01_e/pr252_e.htm (on file with *The University of the Pacific Law Review*) (announcing China's admission to the WTO); *see also* Peter K. Yu et al., *China and the*

While the Chinese patent system experienced considerable changes in its first two decades of existence, its repeated reforms were tailored more to external demands than to changing internal conditions.[45] It was not until the adoption of the third amendment in December 2008 that China was able to make major adjustments to the patent system based on its own needs, interests, conditions, and priorities.[46] As Guo He observed, "The impetus for the early amendments came from outside, whilst the need for the third amendment originated from within China, that is to say, the majority of the third amendment was to meet the needs of the development of the domestic economy and technology originating in China."[47]

Reflecting "the country's growing emphasis on using patents to help develop a knowledge-based economy,"[48] the 2008 Patent Law increased the amount of damages and fines, including statutory damages.[49] The law also allows for parallel importation while introducing the Chinese equivalent of a Bolar exception, which enables generic pharmaceutical producers to import, manufacture, or test a patented product prior to the expiry of the patent "for the purpose of scientific research and experimentation" or "providing information required for administrative examination and approval."[50]

A few months before the adoption of this third amendment, the State Council adopted a new National Intellectual Property Strategy,[51] which "provided a comprehensive plan to improve the creation, utilization, protection, and administration of intellectual property rights."[52] Paragraph 7 specifically emphasized the need for active development of independent or self-controlled intellectual property (*zizhu zhishi chanquan*).[53] Building on this strategy and taking advantage of the new patent law amendment, the State Intellectual

---

WTO: Progress, Perils, and Prospects, 17 COLUM. J. ASIAN L. 1 (2003) (discussing the ramifications of China's entry into the WTO).

45. While the Second Amendment conformed Chinese patent law to TRIPS standards, it also addressed the rapidly changing local conditions, such as "the Chinese leaders' changing attitude towards the rule of law, the emergence of private property rights and local stakeholders, the increasing concerns about ambiguities over relationships in state-owned enterprises, and the government's active push for modernization." Yu, *From Pirates to Partners II*, *supra* note 8, at 908; *see also id*. at 914–22 (discussing these changing conditions).

46. Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Dec. 27, 2008, effective Oct. 1, 2009) (China) [hereinafter 2008 Patent Law].

47. Guo He, *Patents*, *in* CHINESE INTELLECTUAL PROPERTY AND TECHNOLOGY LAWS 25, 28 (Rohan Kariyawasam ed., 2011).

48. Yu, *Building the Ladder*, *supra* note 14, at 10.

49. 2008 Patent Law, *supra* note 46, art. 65.

50. *Id*. art. 69.

51. THE STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, OUTLINE OF THE NATIONAL INTELLECTUAL PROPERTY STRATEGY (2008), http://www.gov.cn/english/2008-06/21/content_1023471.htm [hereinafter NATIONAL INTELLECTUAL PROPERTY STRATEGY] (on file with *The University of the Pacific Law Review*); *see also* Peter K. Yu, *A Half-Century of Scholarship on the Chinese Intellectual Property System*, 67 AM. U. L. REV. 1045, 1079–85 (2018) [hereinafter Yu, *Half-Century of Scholarship*] (discussing the National Intellectual Property Strategy).

52. Yu, *Half-Century of Scholarship*, *supra* note 51, at 1079.

53. NATIONAL INTELLECTUAL PROPERTY STRATEGY, *supra* note 51, ¶ 7.

Property Office ("SIPO"), now the National Intellectual Property Administration of China ("CNIPA"), adopted a National Patent Development Strategy in November 2010.[54] Although the SIPO strategy set a highly ambitious target of two million patents per year by 2015,[55] China surpassed that target in 2012.[56]

Today, China no longer hesitates to offer protection to patents and pharmaceutical products—a significant contrast from three decades ago. Instead, the country has slowly emerged as a major player in the international patent system. In 2019, China even became the world's leader in PCT applications, overtaking the United States for the first time.[57] Based on the latest statistics provided by the World Intellectual Property Organization ("WIPO"), Huawei Technologies, Guangdong Oppo Mobile Telecommunications, the BOE Technology Group, and Ping An Technology—all Chinese companies—ranked among the world's top eight corporate PCT applicants.[58]

At the domestic level, the total number of patent applications has been equally impressive. Based on CNIPA statistics, China processed over 4.3 million patent applications in 2018, with over 4.1 million originating in domestic applicants.[59] While these figures included three types of patents—those for inventions, designs, and utility models—the total number of invention patents issued in China in 2018 (432,147) compared favorably with the total number of utility patents issued in the United States in the same year (306,909).[60]

To be sure, questions have arisen over the quality of patents that the CNIPA and its predecessor, SIPO, have issued.[61] Nevertheless, Chinese firms have been

---

54. STATE INTELLECTUAL PROP. OFFICE, NATIONAL PATENT DEVELOPMENT STRATEGY (2011–2020) (2010), *translated at* http://graphics8.nytimes.com/packages/pdf/business/SIPONatPatentDevStrategy.pdf (on file with *The University of the Pacific Law Review*) [hereinafter NATIONAL PATENT DEVELOPMENT STRATEGY]; *see also* Hao Nan, *"Milestone" Patent Strategy Unveiled*, CHINA DAILY (Nov. 17, 2010), http://www.chinadaily.com.cn/cndy/2010-11/17/content_11560046.htm (on file with *The University of the Pacific Law Review*) (reporting the launch of SIPO's National Patent Development Strategy).

55. *See* NATIONAL PATENT DEVELOPMENT STRATEGY, *supra* note 54, at 4 ("The annual quantity of applying for patents for inventions, utility models and designs [in the country] will reach 2 million.").

56. *See* Peter K. Yu, *When the Chinese Intellectual Property System Hits 35*, 8 QUEEN MARY J. INTELL. PROP. 3, 5 (2018) [hereinafter Yu, *Chinese IP System*] (noting that the two-million target "was surpassed in 2012, three years before the target date").

57. Press Release, WIPO, China Becomes Top Filer of International Patents in 2019 Amid Robust Growth for WIPO's IP Services, Treaties and Finances (Apr. 7, 2020), https://www.wipo.int/pressroom/en/articles/2020/article_0005.html (on file with *The University of the Pacific Law Review*).

58. *Annex 2: Top PCT Applicants*, WORLD INTELL. PROP. ORG. (Mar. 19, 2019), https://www.wipo.int/export/sites/www/pressroom/en/documents/pr_2020_848_annexes.pdf#annex2 (on file with *The University of the Pacific Law Review*).

59. Nat'l Intellectual Prop. Admin. of China [CNIPA], *Total Applications/Grants/In Force for Three Kinds of Patents Received from Home and Abroad*, http://www.cnipa.gov.cn/tjxx/jianbao/year2018/a/a1.html (last visited Aug. 4, 2019) (on file with *The University of the Pacific Law Review*).

60. *Compare* CNIPA, *Distribution of Annual Grants for Three Kinds of Patents Received from Home and Abroad*, http://www.cnipa.gov.cn/tjxx/jianbao/year2018/b/b1.html (last visited Aug. 4, 2019) (on file with *The University of the Pacific Law Review*), *with* U.S. PATENT & TRADEMARK OFFICE, FY 2018 PERFORMANCE AND ACCOUNTABILITY REPORT 178 (2018) [hereinafter 2018 USPTO REPORT].

61. As Dan Prud'homme observed:

actively applying for and obtaining patents at both the European Patent Office and the United States Patent and Trademark Office. Based on the 2017 statistics concerning patent applications filed in the United States, residents from mainland China (32,127) were behind only those of Japan (89,364), South Korea (38,026), and Germany (32,771).[62] According to the European Patent Office, about sixteen percent of its patent filings in that same year originated in China, which trailed behind only the United States and Japan.[63]

As if these statistics were not impressive enough, China ranked fourteenth in the 2019 Global Innovation Index,[64] moving up from seventeenth in 2018, twenty-second in 2017, and twenty-fifth in 2016.[65] As the 2019 report stated, "China continues its upward rise . . . and firmly establishes itself as one of the innovation leaders."[66] The country "was [also] responsible for 24% of the world's [research-and-development] expenditures in 2017, up from only 2.6% in 1996."[67]

Although developments in the electronics and telecommunications industries have provided a key driving force behind China's recent innovative turn—as evidenced by the global leadership Huawei, Oppo, BOE, Ping An, and until recently ZTE have assumed[68]—the country in recent years has also made a major policy push toward actively developing the local pharmaceutical industry. For instance, in February 2006, the State Council released the *National Medium- and Long-Term Plan for Science and Technology Development* (2006–2020), which

---

> While patents are exploding in China and certain innovation is also on the rise, patent quality has not proportionately kept up and in fact the overall strength of China's actual innovation appears overhyped. Statistical analysis . . . not only reveals concerning trends in the quality of China's patents at present, but suggests that while patent filings in China will likely continue to notably grow in the future, patent quality may continue to lag these numbers.

DAN PRUD'HOMME, DULLING THE CUTTING-EDGE: HOW PATENT-RELATED POLICIES AND PRACTICES HAMPER INNOVATION IN CHINA 1 (2012) (emphasis omitted). *See generally* Mark Liang, *Chinese Patent Quality: Running the Numbers and Possible Remedies*, 11 J. MARSHALL REV. INTELL. PROP. L. 478 (2012) (questioning the quality of Chinese patents and offering suggestions for reform).

62. 2018 USPTO REPORT, *supra* note 60, at 184–85.

63. European Patent Office, *European Patent Filings per Country of Origin*, https://www.epo.org/about-us/annual-reports-statistics/annual-report/2017/statistics/patent-filings.html#tab3 (on file with *The University of the Pacific Law Review*) (last visited July 31, 2019).

64. *Rankings*, *in* GLOBAL INNOVATION INDEX 2019, *supra* note 3, at xxxiv, xxxiv.

65. *Rankings*, *in* GLOBAL INNOVATION INDEX 2018: ENERGIZING THE WORLD WITH INNOVATION xx, xx (Soumitra Dutta et al. eds., 2018); *Rankings*, *in* GLOBAL INNOVATION INDEX 2017: INNOVATION FEEDING THE WORLD xviii, xviii (Soumitra Dutta et al. eds., 2017); *Rankings*, *in* GLOBAL INNOVATION INDEX 2016: WINNING WITH GLOBAL INNOVATION xviii, xviii (Soumitra Dutta et al. eds., 2016).

66. Soumitra Dutta et al., *The Global Innovation Index 2019*, in GLOBAL INNOVATION INDEX 2019, *supra* note 3, at 1, 9.

67. *Id*. at 3.

68. *Annex 2: Top PCT Applicants*, *supra* note 58; *see also* Whitney Stenger, *Mark Cohen: Global Intellectual Property Ambassador*, 15 SMU SCI. & TECH. L. REV. 41, 45–46 (2011) ("There have not been many blockbuster pharma products coming out of China, so one cannot really equate 10,000 patents in China's [information technology] sector to 10,000 patents in the pharma sector." (quoting Mark Cohen, the former senior intellectual property attaché at the U.S. Embassy in Beijing)).

listed biotechnology as one of the eight frontier technologies.[69] A decade later, the State Council issued a notice for the *Made in China 2025* strategic plan, which also identified biomedicine and high-performance medical devices as one of the ten priority sectors.[70] Among the medical products and technologies that China intends to develop are "biologic-based therapeutics, such as antibody drugs, antibody-drug conjugates, new structural proteins, polypeptide drugs, and new vaccines; technologies to support individualized drug treatments (i.e., precision medicine); and breakthrough technologies, such as induced pluripotent stem cells."[71]

In addition, China has played important roles in pushing for greater use and development of artificial intelligence ("AI") and machine learning in the health area.[72] As a contributor to *Global Innovation Index 2019* stated:

> Th[e] growth in national health expenditures is creating opportunities for medical AI in China. According to Tractica's forecast, China's AI medical market is developing rapidly, with the market size soaring from 9.661 billion yuan in 2016, and 13.65 billion yuan in 2017, to 20.4 billion yuan in 2018, maintaining a compound annual growth rate of more than 40%. At the same time, Chinese medical institutions and businesses are taking a proactive attitude towards AI. Nearly 80% of hospitals and medical companies are planning to, or already have, carried out medical AI applications and more than 75% of hospitals believe that such applications will become popular in the future.[73]

III. CHANGING PHARMACEUTICAL LANDSCAPE

In April 2018, the National Medical Products Administration of China,

69. THE STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, THE NATIONAL MEDIUM- AND LONG-TERM PLAN FOR SCIENCE AND TECHNOLOGY DEVELOPMENT (2006–2020): AN OUTLINE pt. V(1) (2006), https://www.itu.int/en/ITU-D/Cybersecurity/Documents/National_Strategies_Repository/China_2006.pdf (on file with *The University of the Pacific Law Review*).

70. *See* THE STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, MADE IN CHINA 2025 pt. VI (2015), http://www.gov.cn/zhengce/content/2015-05/19/content_9784.htm (on file with *The University of the Pacific Law Review*); *see also* U.S. CHAMBER OF COMMERCE, MADE IN CHINA 2025: GLOBAL AMBITIONS BUILT ON LOCAL PROTECTIONS 10 (2017) (identifying the ten priority sectors).

71. GRYPHON SCIENTIFIC, LLC & RHODIUM GROUP, LLC, CHINA'S BIOTECHNOLOGY DEVELOPMENT: THE ROLE OF US AND OTHER FOREIGN ENGAGEMENT: A REPORT PREPARED FOR THE U.S.–CHINA ECONOMIC AND SECURITY REVIEW COMMISSION 38 (2019) [hereinafter CHINA'S BIOTECHNOLOGY DEVELOPMENT STUDY]; *see also* WHO CHINA STUDY, *supra* note 1, at 20 ("China is placing a strong emphasis on development of capacity for biologic drugs, and in the near- to medium-term sees the introduction of biosimilar drugs as a major domestic and global market opportunity.").

72. *See generally* LEE KAI-FU, AI SUPERPOWERS: CHINA, SILICON VALLEY, AND THE NEW WORLD ORDER (2018) (discussing the development relating to artificial intelligence in China).

73. Ma, *supra* note 3, at 103 (footnote omitted); *see also* Peter K. Yu, *Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals*, 6 TEX. A&M L. REV. ARGUENDO 22, 22 (2018) ("The introduction of big data analytics has transformed the fields of biotechnology and bioinformatics while ushering in major advances in drug development, clinical practices, and medical financing.").

formerly the Food and Drug Administration of China, released the draft Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products.[74] Article 5 of these measures not only provides six years of protection to data submitted for the regulatory approval of innovative drugs (*chuangxin yao*),[75] but also twelve years of protection to undisclosed test or other data for innovative therapeutic biologics (*chuangxin zhiliao yong shengwu zhipin*).[76] While the WTO accession protocol required China to offer at least six years of protection to undisclosed test or other data for pharmaceutical products[77]—a duration that Article 39.3 of the TRIPS Agreement does not require[78]—the accession protocol did not include any provision on biological products.[79] In fact, the protections for these products have been the subject of major controversies in the negotiations for TRIPS-plus bilateral, regional, and plurilateral agreements, including the Trans-Pacific Partnership ("TPP") Agreement.[80]

---

74. Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products, https://chinaipr2.files.wordpress.com/2018/04/draftdataexclusivityrules.doc (China) [hereinafter Provisional Measures] (on file with *The University of the Pacific Law Review*).

75. *Id*. art. 5.

76. *Id*.; *see also* WHO CHINA STUDY, *supra* note 1, at 19–21 (discussing the growing development of biological products in China).

77. As the report of the Working Party on the Accession of China stated:

> The representative of China . . . confirmed that China would, in compliance with Article 39.3 of the TRIPS Agreement, provide effective protection against unfair commercial use of undisclosed test or other data submitted to authorities in China as required in support of applications for marketing approval of pharmaceutical or of agricultural chemical products which utilized new chemical entities, except where the disclosure of such data was necessary to protect the public, or where steps were taken to ensure that the data are protected against unfair commercial use. This protection would include introduction and enactment of laws and regulations to make sure that no person, other than the person who submitted such data, could, without the permission of the person who submitted the data, rely on such data in support of an application for product approval for a period of at least six years from the date on which China granted marketing approval to the person submitting the data. During this period, any second applicant for market authorization would only be granted market authorization if he submits his own data. This protection of data would be available to all pharmaceutical and agricultural products which utilize new chemical entities, irrespective of whether they were patent-protected or not. The Working Party took note of these commitments.

World Trade Org., *Report of the Working Party on the Accession of China* ¶ 284, WTO Doc. WT/ACC/CHN/49 (Oct. 1, 2001) [hereinafter *WTO Accession Report*].

78. *See* TRIPS Agreement, *supra* note 11, art. 39.3 (omitting the durational requirement); *see also* Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46 FLA. ST. U. L. REV. 641, 651–52 (2019) [hereinafter Yu, *Data Exclusivities*] (discussing the lack of the durational requirement in Article 39.3 of the TRIPS Agreement).

79. *See* Srividhya Ragavan, *The (Re)Newed Barrier to Access to Medication: Data Exclusivity*, 51 AKRON L. REV. 1163, 1185 (2017) [hereinafter Ragavan, *(Re)Newed Barrier*] ("On the face of it, biologics are not included within the scope of Article 39.3's requirement to protect new chemical entities. The [new chemical entities] should not, by definition, include biologics." (footnote omitted)); Yu, *Data Exclusivities*, *supra* note 78, at 689–90 ("Article 39.3 of the TRIPS Agreement does not grant protection to biologics because those products are not considered 'new chemical entities' within the meaning of the Agreement.").

80. *See* Frederick M. Abbott, *The Evolution of Public Health Provisions in Preferential Trade and Investment Agreements of the United States*, *in* CURRENT ALLIANCES IN INTERNATIONAL INTELLECTUAL PROPERTY LAWMAKING: THE EMERGENCE AND IMPACT OF MEGA-REGIONALS 45, 55 (Pedro Roffe & Xavier

More recently, China proposed the fourth amendment to the Patent Law.[81] Article 43 of that draft amendment grants a limited extension of the patent term for up to five years to compensate for the time lost when a pharmaceutical product is undergoing regulatory review.[82] Should the duration of patent protection be extended under this provision, the maximum protection will last for fourteen years.[83] The proposed Article 43 parallels the Hatch-Waxman Act of 1984 in the United States[84] and similar provisions on patent term extension in TRIPS-plus bilateral, regional, and plurilateral agreements.[85]

Taken together, these two sets of regulatory changes are important at both the national and international levels. Domestically, China continues to face serious problems in the public health arena, as illustrated by its past problems with SARS, bird flu, and swine flu and its ongoing problem with COVID-19.[86] With a gross national income per capita of $9470 in 2018,[87] China now ranks in the

Seuba eds., 2017) (noting that "negotiation of the duration of the biologics exclusivity period was perhaps the most controversial part of the TPP negotiations"); Burcu Kilic & Courtney Pine, *Decision Time on Biologics Exclusivity: Eight Years Is No Compromise*, INTELL. PROP. WATCH (July 27, 2015), http://www.ip-watch.org/2015/07/27/decision-time-on-biologics-exclusivity-eight-years-is-no-compromise/ (on file with *The University of the Pacific Law Review*) ("As the Trans-Pacific Partnership . . . negotiations approach their endgame, biologics exclusivity is still considered 'one of the most difficult outstanding issues in the negotiation.'").

81. Patent Law of People's Republic of China (Draft) (2019) [hereinafter Draft Fourth Amendment], *translated at* https://chinaipr2.files.wordpress.com/2019/01/2019-draft-patent-law-amendment-line-by-line-en-and-cn-by-anjie.doc (on file with *The University of the Pacific Law Review*).

82. *See id*. art. 43 (providing up to five years of extension of the patent term for innovative drugs); *see also* Tim Jackson, *China to Allow Patent Extension of Term?*, ROUSE (May 16, 2018), https://www.rouse.com/magazine/news/china-to-allow-patent-extension-of-term/ (on file with *The University of the Pacific Law Review*) (discussing the potential extension of the patent term for pharmaceutical products in China).

83. *See* Draft Fourth Amendment, *supra* note 81, art. 43 (limiting the maximum protection to fourteen years).

84. *See* 35 U.S.C. § 156 (2018) (providing a limited extension of the patent term based on the period during which a pharmaceutical product undergoes regulatory review).

85. *See, e.g.*, Dominican Republic–Central America Free Trade Agreement, art. 15.9.6, Aug. 5, 2004, http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text (on file with *The University of the Pacific Law Review*); United States–Australia Free Trade Agreement, Austl.–U.S., art. 17.9.8, May 18, 2004, https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text (on file with *The University of the Pacific Law Review*); United States–Singapore Free Trade Agreement, Sing.–U.S., art. 16.7.8, May 6, 2003, https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text (on file with *The University of the Pacific Law Review*).

86. *See* NINA HACHIGIAN & MONA SUTPHEN, THE NEXT AMERICAN CENTURY: HOW THE U.S. CAN THRIVE AS OTHER POWERS RISE 41 (2010) ("When it comes to influenza, China is both the problem and the solution. Asia, especially southern China, is ground zero for flu outbreaks."); Yu, *Virotech Patents*, *supra* note 23, at 1652 ("Because of the climate, crowdedness, and huge population, China and countries in Southeast Asia have . . . been the breeding places for outbreaks of influenza and other infectious diseases."); Press Release, WHO, Pneumonia of Unknown Cause—China (Jan. 5, 2020), https://www.who.int/csr/don/05-january-2020-pneumonia-of-unkown-cause-china/en/ (on file with *The University of the Pacific Law Review*) (announcing China's reports of "pneumonia of unknown etiology," which became COVID-19, to the World Health Organization).

87. *GNI per Capita, Atlas Method (Current US$)*, WORLD BANK, https://data.worldbank.org/indicator/NY.GNP.PCAP.CD (last visited July 31, 2019) (on file with *The University of the Pacific Law Review*).

middle among the upper-middle-income economies.[88] In view of these conditions and China's continued eagerness to assume leadership in the developing world, the recently proposed changes in the pharmaceutical arena are indeed surprising, as these changes will move China's policy position closer to that of developed countries.[89] Such a policy shift is particularly troubling considering the aging Chinese population, which will require higher levels of healthcare while imposing a greater internal demand for pharmaceutical and biological products.[90]

Globally, having twelve years of protection for undisclosed test or other data for biological products in China is equally significant, because this lengthy duration is not only the current U.S. standard, but also longer than what existing TRIPS-plus bilateral, regional, and plurilateral agreements provide.[91] Although U.S. negotiators had pushed aggressively for this particular standard in the TPP negotiations,[92] the TPP negotiating parties eventually settled on protection for "at least eight years from the date of first marketing approval."[93] Even more limiting, the TPP Agreement guarantees only five years of such protection through market exclusivity, while it offers protection for the remaining years through either market exclusivity or "other measures," depending on the preference of the

88. *See World Bank Country and Lending Groups*, WORLD BANK, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups (last visited July 31, 2019) (on file with *The University of the Pacific Law Review*) ("For the current 2020 fiscal year, . . . upper middle-income economies are those with a [gross national income] per capita between $3,996 and $12,375 . . . .").

89. *See* Peter K. Yu, *Five Oft-repeated Questions About China's Recent Rise as a Patent Power*, 2013 CARDOZO L. REV. DE NOVO 78, 113 [hereinafter Yu, *Five Oft-Repeated Questions*] ("It will . . . be no surprise if China is aligned with the developing world with respect to certain issues, but with the developed world with respect to others."); *see also* Peter K. Yu, *The RCEP and Trans-Pacific Intellectual Property Norms*, 50 VAND. J. TRANSNAT'L L. 673, 722 (2017) [hereinafter Yu, *RCEP and Trans-Pacific Norms*] ("Although [China, India, and other emerging countries] have yet to embrace the very high protection and enforcement standards found in the European Union, Japan, or the United States, they now welcome standards that are higher than what is currently available in the Asia-Pacific region.").

90. *See* WHO CHINA STUDY, *supra* note 1, at 1 ("China has a population of approximately 1.4 billion people, and it is a population that is rapidly aging. This will increase demand for pharmaceuticals, and place increasing burden on the health care budget and system as a whole."); *Characterising Eastern China's Pharmaceutical Manufacturing Market: Shandong and Jiangsu*, PHARMACEUTICAL TECH. (June 13, 2019), https://www.pharmaceutical-technology.com/comment/china-pharmaceutical-industry-2019/ (on file with *The University of the Pacific Law Review*) (noting that "the population [in China] will become increasingly more aged and require greater levels of medical treatment"); Ren Shuli, *Selling Drugs Is No Longer a Free Lunch in China*, BLOOMBERG (Jan. 2, 2019), https://www.bloomberg.com/opinion/articles/2019-01-02/china-s-drug-market-is-no-longer-a-free-lunch (on file with *The University of the Pacific Law Review*) (noting "a rapidly aging population and 4 million new cancer patients each year" in China).

91. *See* 42 U.S.C. § 262(k)(7)(A) (2018) (providing twelve years of protection to undisclosed test or other data for biological products).

92. *See* Kilic & Pine, *supra* note 80 ("In late 2013, the United States Trade Representative . . . proposed 12 years of exclusivity (which functions as marketing exclusivity rather than data exclusivity) for biologics in the TPP, even though this contradicts and is mutually exclusive with the Administration's domestic policy proposals.").

93. Trans-Pacific Partnership Agreement, art. 18.51.1(a), Feb. 4, 2016, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [hereinafter TPP Agreement] (on file with *The University of the Pacific Law Review*).

relevant TPP party.[94] As if these compromises had not weakened the international standard for biological products significantly enough, the TPP provision was suspended in its entirety[95] following the United States' withdrawal from the regional pact[96] and the establishment of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership ("CPTPP").[97] As a result, the high eight-year standard for undisclosed test or other data for biological products is no longer binding on the eleven CPTPP signatories.

In fall 2018, the United States successfully resuscitated the TPP standard through the negotiation of the United States–Mexico–Canada Agreement ("USMCA").[98] Aiming to replace the North American Free Trade Agreement ("NAFTA"),[99] the USMCA was signed in November 2018.[100] Article 20.49 in the signed text offers protection to undisclosed test or other data submitted for the regulatory approval of biological products, which lasts "for a period of at least ten years from the date of first marketing approval of that product."[101] Although ten years is shorter than the duration in the United States, it is still longer than that of both Canada (eight years) and Mexico (no protection).[102] The ten-year duration is also two years longer than the TPP standard, which was until then the

94. *Id*. art. 18.51.1(b)(ii).

95. *See* Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Mar. 8, 2018, art. 2, Annex, https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-concluded-but-not-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text [hereinafter CPTPP] (on file with *The University of the Pacific Law Review*) (suspending articles 18.50 and 18.51 of the TPP Agreement); *see also* Peter K. Yu, *Thinking About the Trans-Pacific Partnership (and a Mega-Regional Agreement on Life Support)*, 20 SMU SCI. & TECH. L. REV. 97, 105 (2017) [hereinafter Yu, *Thinking About TPP*] (discussing the CPTPP's suspension of select TPP provisions).

96. *See* Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement, 82 Fed. Reg. 8497 (Jan. 23, 2017) (directing the United States Trade Representative to "withdraw the United States as a signatory to the [TPP and] . . . from TPP negotiations"); *see also* Yu, *Thinking About TPP*, *supra* note 95, at 101–10 (discussing the United States' withdrawal from the TPP Agreement and its aftermath).

97. CPTPP, *supra* note 95; *see also* Yu, *Thinking About the TPP*, *supra* note 95, at 104–06 (discussing the CPTPP). The later agreement was signed in Santiago, Chile in March 2018 and entered into force at the end of that year.

98. United States–Mexico–Canada Agreement, Can.–Mex.–U.S., Nov. 30, 2018, https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement [hereinafter USMCA] (on file with *The University of the Pacific Law Review*).

99. North American Free Trade Agreement, Can.–Mex.–U.S., Dec. 17, 1992, 32 I.L.M. 289 (1993).

100. *See* Glenn Thrush, *Trump Says He Plans to Withdraw from Nafta*, N.Y. TIMES (Dec. 2, 2018), https://www.nytimes.com/2018/12/02/us/politics/trump-withdraw-nafta.html (on file with *The University of the Pacific Law Review*) (reporting President Trump's announcement of his intention to withdraw the United States from NAFTA).

101. USMCA, *supra* note 98, art. 20.49; *see also* Yu, *Data Exclusivities*, *supra* note 78, at 682–83 (discussing Article 20.49 of the USMCA).

102. *See* 42 U.S.C. § 262(k)(7)(A) (2018) (providing twelve years of protection to undisclosed test or other data for biological products); Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative (July 11, 2019), https://schakowsky.house.gov/uploads/lighthizermeds.pdf [hereinafter Schakowsky Letter] (on file with *The University of the Pacific Law Review*) ("Mexico . . . has no additional exclusivity period for biologics, and . . . Canada . . . has an eight-year period.").

high watermark for international protection in this area.[103]

Unlike Article 18.51 of the TPP Agreement, the USMCA provision does not allow for substitutional protection "through other measures."[104] The only flexibility Canada and Mexico received was a transition clause, which delays protection for five years.[105] It is therefore no surprise that U.S. policymakers were so concerned about the high protections for biological products under the new agreement that they called on the Office of the United States Trade Representative ("USTR") to "amend the USMCA to increase competition and enhance patient access to more affordable prescription drugs," including biological products.[106] In December 2019, USMCA signatories amended the agreement by removing Article 20.49.[107] As a result, the USMCA no longer protects undisclosed test or other data for biological products, similar to the CPTPP.

In sum, the proposed twelve years of protection for undisclosed test or other data for biological products in China is higher than the standard laid down in even the most aggressive TRIPS-plus bilateral, regional, and plurilateral agreements. That lengthy duration also puts China in parity with the United States.[108] While such stronger protection would certainly attract foreign providers of biological products to undertake research and development in China,[109] such protection also reveals China's eagerness to become more assertive in the pharmaceutical arena.[110] Just like how Chinese companies such as Huawei, ZTE,

---

103. *See* TPP Agreement, *supra* note 93, art. 18.51.1 (providing eight years of protection to undisclosed test or other data for biological products).

104. *Compare* TPP Agreement, *supra* note 93, art. 18.51.1(b), *with* USMCA, *supra* note 98, art. 20.49.

105. *See* USMCA, *supra* note 98, art. 20.90.3(e) (delaying the protection under Article 20.49 for five years in Canada); *id*. art. 20.90.4(c) (delaying the protection under Article 20.49 for five years in Mexico).

106. Schakowsky Letter, *supra* note 102. As the letter stated, "Unless the USMCA text is amended, it would limit Congress' ability to adjust the biologics exclusivity period, instead locking the US into policies that keep cancer and other drug prices high while exporting this model to Mexico . . . and . . . Canada . . . ." *Id*.; *see also* Allison Inserro, *House Democrats Ask US Trade Representative to Drop Biologics Language from USMCA*, CTR. FOR BIOSIMILARS (July 12, 2019), https://www.centerforbiosimilars.com/news/house-democrats-ask-us-trade-representative-to-drop-biologics-language-from-usmca (on file with *The University of the Pacific Law Review*) (reporting the letter).

107. Protocol of Amendment to the Agreement Between the United States of America, the United Mexican States, and Canada art. 3.E, Can.–Mex.–U.S., Dec. 10, 2019, https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Protocol-of-Amendments-to-the-United-States-Mexico-Canada-Agreement.pdf (on file with *The University of the Pacific Law Review*).

108. *Compare* Provisional Measures, *supra* note 74, art. 5, *with* 42 U.S.C. § 262(k)(7)(A) (2018).

109. *See* Yu, *Data Exclusivities*, *supra* note 78, at 696 ("Stronger protections for undisclosed test or other data for pharmaceutical and biological products will certainly make China a much more appealing place for conducting clinical trials."); Mark Cohen, *Draft of Data Exclusivity Rules Released by CFDA*, CHINA IPR (Apr. 26, 2018), https://chinaipr.com/2018/04/26/draft-of-data-exclusivity-rules-released-by-cfda/ (on file with *The University of the Pacific Law Review*) ("As a policy matter, [the proposed Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products] appears intended to help encourage conducting clinical trials in China as well as new product introduction into the Chinese market[.]").

110. *See* CHINA'S BIOTECHNOLOGY DEVELOPMENT STUDY, *supra* note 71, at 3 ("As China's biotechnology industry develops, we are likely to see continued advancement in medical biotechnology, especially in biologics, genomics, and molecular diagnostics. Chinese biologics companies may move further

and BOE have built their portfolios of PCT applications, China is now actively undertaking legal and regulatory reforms to create national champions in the pharmaceutical arena.

IV. RAMIFICATIONS

In view of China's growing assertiveness in this arena and the changing domestic and global pharmaceutical landscapes, this Part explores the ramifications such assertiveness will have in the intellectual property and public health areas. Specifically, the discussion focuses on three sets of ramifications: (1) the changing discourse on intellectual property developments in China; (2) the internal challenges that confront the country at this time of policy transition; and (3) the global complications that will affect the future development of the international trading and intellectual property systems.

A. Changing Discourse

Since the mid-1980s, China has become the poster child of intellectual property piracy and counterfeiting.[111] Every year, the USTR puts the country on its watch list or priority watch list.[112] In the past three years, its out-of-cycle reviews have placed Alibaba's Taobao on the list of notorious online markets.[113] If pharmaceuticals are mentioned in the Chinese context, the discussion often focuses on counterfeit drugs.[114] For example, in *China Rx*, Rosemary Gibson and

toward producing innovative drugs."); WHO CHINA STUDY, *supra* note 1, at 17, 29 ("Chinese manufacturers are moving away from reliance on API production toward [finished pharmaceutical products], in part because of generally low profit margins associated with APIs. . . . The China Government is strongly encouraging R&D in the pharmaceutical sector, with respect to new biologic products." (footnote omitted)); Yu, *Data Exclusivities*, *supra* note 78, at 694 ("China wants to develop a research-based pharmaceutical industry."); *see also* LI YAHONG, IMITATION TO INNOVATION IN CHINA: THE ROLE OF PATENTS IN BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES 54 (2010) ("China has advantages in producing 'me too' drugs because its capacity to conduct organic synthesis is very strong after many years of China's being the target for outsourced [multinational pharmaceutical companies'] business.").

111. *See* sources cited *supra* note 8.

112. *See* Peter K. Yu, *Intellectual Property and Asian Values*, 16 MARQ. INTELL. PROP. L. REV. 329, 380 (2012) (listing the USTR's Special 301 actions from 2001 to 2011). The notable exception is during the honeymoon period following China's accession to the WTO in December 2001. In April 2005, the USTR elevated China back to the Priority Watch List. *See* Yu, *From Pirates to Partners II*, *supra* note 8, at 925.

113. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2018 OUT-OF-CYCLE REVIEW OF NOTORIOUS MARKETS 26–27 (2019); OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2017 OUT-OF-CYCLE REVIEW OF NOTORIOUS MARKETS 20–23 (2018); OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2016 OUT-OF-CYCLE REVIEW OF NOTORIOUS MARKETS 12–13 (2016). Alibaba "was last on th[at] list in 2012." Scott Cendrowski, *Why Alibaba Can't Complain About Its Return to the "Notorious" Counterfeit Market List*, FORTUNE (Dec. 22, 2016), https://fortune.com/2016/12/22/alibaba-taobao-counterfeit-goods-platform/ (on file with *The University of the Pacific Law Review*).

114. As Daniel Chow observed:

> China is the largest exporter of counterfeit and substandard drugs in the world. It is also a major supplier of both genuine and substandard [APIs]. China makes counterfeit, substandard drugs and APIs for use in China and, perhaps more importantly, for export to countries around the world.

Janardan Prasad Singh warned about the increasing risks of the growing dependence of the global supply chain for pharmaceutical products and vitamins on the APIs originating in China.[115] In the past few months, commentators also expressed similar concerns in relation to the potential shortages of medicines amid the COVID-19 pandemic.[116]

While piracy and counterfeiting remain relevant to any discussion of intellectual property protection and enforcement in China, and such discussion is unlikely to go away in the near future,[117] one cannot overlook the many important developments that are now happening in the country. In the past decade, China has tremendously increased its innovative capabilities, relying on innovation models that are sometimes different from those found in the Western world.[118] China has also made notable achievements in biotechnology (including genomics and stem cell research), space technology, information technology,

---

> These counterfeit exports can cause serious health problems, even deaths, and can subject MNCs [multinational corporations] to liability for these injuries. In addition, counterfeits can cause damage to the business reputation of MNCs and the goodwill associated with their brands. 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.

Daniel C.K. Chow, *Three Major Problems Threatening Multinational Pharmaceutical Companies Doing Business in China*, 19 COLUM. SCI. & TECH. L. REV. 46, 78 (2017) (footnotes omitted).

115. ROSEMARY GIBSON & JANARDAN PRASAD SINGH, CHINA RX: EXPOSING THE RISKS OF AMERICA'S DEPENDENCE ON CHINA FOR MEDICINE (2018).

116. *See* Ana Swanson, *Coronavirus Spurs U.S. Efforts to End China's Chokehold on Drugs*, N.Y. TIMES (Mar. 11, 2020), https://www.nytimes.com/2020/03/11/business/economy/coronavirus-china-trump-drugs.html (on file with *The University of the Pacific Law Review*) ("The global spread of the coronavirus is reigniting efforts by the Trump administration to encourage more American manufacturing of pharmaceuticals and reduce dependence on China for the drugs and medical products that fuel the federal health care system."); Guy Taylor, *"Wake-Up Call": Chinese Control of U.S. Pharmaceutical Supplies Sparks Growing Concern*, WASH. TIMES (Mar. 17, 2020), https://www.washingtontimes.com/news/2020/mar/17/china-threatens-restrict-critical-drug-exports-us/ (on file with *The University of the Pacific Law Review*) ("With the coronavirus crisis threatening to strain the U.S. government's large stockpiles of such drugs, health experts warn that China's own outbreak and related societal shutdown could mean major shortages ahead as Chinese factories struggle to keep up production of the APIs.").

117. *See* Yu, *Chinese IP System*, *supra* note 56, at 6–7 (noting that "piracy and counterfeiting problems [in China] continue to exist, and are unlikely to go away any time soon"); *see also* Peter K. Yu, *Three Questions That Will Make You Rethink the U.S.–China Intellectual Property Debate*, 7 J. MARSHALL REV. INTEL. PROP. L. 412, 423 (2008) ("[S]tronger intellectual property protection will appear in Beijing, Shanghai, Guangzhou, and other major cities and coastal regions. Meanwhile, the massive piracy and counterfeiting problems will stay in China, migrating from the country's developed parts to its less developed parts.").

118. *See* Peter K. Yu, *Imitative Pasts, Innovation Pathways and Intellectual Property*, *in* INNOVATION AND TRIPLE HELIX (Anselm Kamperman Sanders ed., forthcoming 2021) (discussing China's innovation paths); Yu, *Half-Century of Scholarship*, *supra* note 51, at 1103–07 (identifying a growing body of scholarship that examines the fast-growing innovative capabilities of Chinese firms and the alternative forms of innovation in China). For discussions of innovation in China, see generally DAN BREZNITZ & MICHAEL MURPHREE, RUN OF THE RED QUEEN: GOVERNMENT, INNOVATION, GLOBALIZATION, AND ECONOMIC GROWTH IN CHINA (2011); JOHN L. ORCUTT & SHEN HONG, SHAPING CHINA'S INNOVATION FUTURE: UNIVERSITY TECHNOLOGY TRANSFER IN TRANSITION (2011); TAN YINGLAN, CHINNOVATION: HOW CHINESE INNOVATORS ARE CHANGING THE WORLD (2011); ZENG MING & PETER J. WILLIAMSON, DRAGONS AT YOUR DOOR: HOW CHINESE COST INNOVATION IS DISRUPTING GLOBAL COMPETITION (2007).

nanotechnology, and advanced energy technology.[119]

In addition, as Part II has noted, China has now become a world leader in filing international and foreign patent applications.[120] In terms of health patent publications, the *Global Innovation Index 2019* placed China among the top three in the world in the areas of biotechnology, pharmaceuticals, and medical technology, based on publications from 2010 to 2017.[121] From 1985 to 2017, "China ranked fourth in the total number of healthcare AI patent applications filed, contributing to 12% of the total."[122] In 2016, China already "surpassed Japan and the European Union to become the world's second largest healthcare AI applicant . . . , which reflects the strong momentum of medical technology innovation in China."[123]

At some point, we will have to recognize the incomplete, or paradoxical, nature of the ongoing discourse about intellectual property developments in China. In the same month that the United States filed its second WTO complaint against China for providing inadequate intellectual property protection and violating the TRIPS Agreement,[124] WIPO announced that China had overtaken Japan to become the country with the second largest number of PCT applications in the world.[125] Likewise, although U.S. politicians and policymakers have been quick to criticize the lack of intellectual property protection in the country, many of them express concern about China's growing technological competition with the United States.[126] If traditional innovation and intellectual property theories are correct that a country needs good innovation and intellectual property policies to strengthen technological capabilities, the discourse cannot continue to emphasize the two ends of the spectrum without also recognizing developments in the middle.

To be sure, the "vast size, political and economic complexities, and often internally inconsistent laws and policies" of China have made it possible for the simultaneous occurrence of developments at these two polarized ends.[127] In fact, my past scholarship noted the possibility for China to "emerge as a highly

119. *See* ORCUTT & SHEN, *supra* note 118, at ix (identifying these achievements).

120. *See supra* text accompanying notes 57–58 and 62–63.

121. Dutta et al., *supra* note 66, at 48.

122. Ma, *supra* note 3, at 104.

123. *Id*.

124. *Second TRIPS Complaint*, *supra* note 10.

125. Press Release, WIPO, China Drives International Patent Applications to Record Heights; Demand Rising for Trademark and Industrial Design Protection (Mar. 21, 2018), https://www.wipo.int/pressroom/en/articles/2018/article_0002.html (on file with *The University of the Pacific Law Review*).

126. *See* SECTION 301 INVESTIGATION REPORT, *supra* note 9, at 10–18 (documenting China's technology drive); CHINA'S BIOTECHNOLOGY DEVELOPMENT STUDY, *supra* note 71, at 12–44 (discussing the state of and changes in China's biotechnology industry).

127. Peter K. Yu, *Intellectual Property, Asian Philosophy and the Yin-Yang School*, 7 WIPO J. 1, 12 (2015) [hereinafter Yu, *Yin-Yang School*]; *see also* Yu, *Five Oft-Repeated Questions*, *supra* note 89, at 81 ("In the future, China is likely to see both the yin of continued massive piracy and counterfeiting and the yang of China's rise as an intellectual property power *at the same time*.").

innovative power while at the same time remaining as the world's biggest pirate nation."[128] To the extent that policymakers and commentators are willing to entertain such a dualistic—and somewhat paradoxical—possibility, it will be important for them to devote greater time, effort, and energy to exploring the laws, policies, and complementary measures that China will need to address these seemingly oxymoronic developments.[129] While history has shown countries such as the United States, Japan, and South Korea crossing over from pirate nations to countries respectful of intellectual property rights, we do not yet have good theories or empirical data to account for countries that have been active in both directions.[130]

B. Internal Challenges

The second area that deserves greater attention concerns the internal challenges that the changing pharmaceutical landscape will create within China. A notable characteristic of this vast, complex country is its highly uneven economic and technological developments. Commentators have widely noted the country's wide regional disparities[131] and high Gini coefficient, which indicates the gap between the rich and the poor.[132] To a large extent, China has the characteristics of "a 'country of countries,' rather than a homogenous one."[133] It would fit what Nobel Laureate Michael Spence described as a "dual economy,"

---

128. Yu, *Yin-Yang School*, *supra* note 127, at 13.

129. *See id*. (noting the "need to come up with new theories, concepts, vocabularies and even schools of thought to address th[e] unforeseen situation" in which a country will emerge as a highly innovative power while at the same time remaining as the world's biggest pirate nation); *see also* Peter K. Yu, *A Spatial Critique of Intellectual Property Law and Policy*, 74 WASH. & LEE L. REV. 2045, 2123–27 (2017) [hereinafter Yu, *Spatial Critique*] (discussing the possibility of developing differentiated intellectual property standards at the subnational level).

130. *See* Yu, *Five Oft-Repeated Questions*, *supra* note 89, at 113–14 ("Although internal contradictions are not uncommon in China, especially when one takes into account the country's uneven regional, sectoral, and technological developments, this complex, dualistic, and highly dynamic picture suggests the possibility for a new phenomenon that the world has never seen before." (footnote omitted)); Yu, *Yin-Yang School*, *supra* note 127, at 13 ("[A]lthough history has seen countries crossing over from the less respectful side of the intellectual property divide to the more promising one—the United States, Japan and South Korea being some of the more notable instances—no country has ever stayed on both ends of the spectrum at the same time.").

131. As I noted in an earlier article:

> China is large, complex, diverse, and "sometimes internally contradictory." The Chinese speak different languages, enjoy different cuisines, grow up with different cultures, and subscribe to different historical and philosophical traditions. Conditions in Beijing are often very different from those in Guangzhou, intellectual property strategies that are effective in Shanghai are likely to fail in a village in western China, and the trade patterns found in the coastal areas are very different from those found in the inland areas.

Peter K. Yu, *International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia*, 2007 MICH. ST. L. REV. 1, 23 [hereinafter Yu, *Regime Complex*] (footnote omitted).

132. *See* Peter K. Yu, *Foreword* to PATENTS AND INNOVATION IN MAINLAND CHINA AND HONG KONG: TWO SYSTEMS IN ONE COUNTRY COMPARED xiv, xvii (Li Yahong ed., 2017) ("According to the National Bureau of Statistics, [in 2016] China had a Gini coefficient of 0.465, one of the highest in the world.").

133. Yu, *From Pirates to Partners II*, *supra* note 8, at 963.

which consists of "a relatively rich one whose growth is constrained by the normal forces that constrain the growth of relatively advanced economies, and a poor one where the early-stage growth dynamics . . . just didn't start, owing to its separation from the modern domestic economy and the global economy."[134]

More specifically in the intellectual property area, China has experienced highly uneven technological developments. Consider, for instance, the number of invention patents filed and granted in its different provinces and autonomous regions. Based on CNIPA statistics, in 2018 Guangdong, Jiangsu, and Zhejiang—the provinces with the three largest volumes of applications—had 216,469, 198,801, and 143,081 applications, respectively.[135] Meanwhile, Jilin, Yunnan, and Shanxi (those provinces that ranked eighteenth to twentieth) had only 10,530, 9,606, and 9,395 applications, respectively.[136] In the same year, the total numbers of patent grants for Guangdong, Jiangsu, and Zhejiang were 53,259, 42,019, and 32,550, respectively.[137] By contrast, the total numbers for Jilin, Yunnan, and Shanxi were 2,868, 2,297, and 2,284, respectively.[138] For either patent applications or grants, the figures for the less developed provinces were less than one-tenth of the figures for their more developed counterparts. If we include in the second group those provinces and autonomous regions that have fewer than 4,000 patent applications and 1,000 patent grants, such as Inner Mongolia, Xinjiang, Ningxia, Hainan, Qinghai, and Tibet, the statistical contrasts between these two groups will become even starker.[139]

From a policy standpoint, these disparities are highly significant. In fact, the remarkably uneven economic and technological developments in China have suggested the country's need to develop schizophrenic intellectual property policies.[140] What policies China needs in one region may not be the same as what

---

134. MICHAEL SPENCE, THE NEXT CONVERGENCE: THE FUTURE OF ECONOMIC GROWTH IN A MULTISPEED WORLD 204 (2011) (referring to the "dual economy" in Brazil); *see also* FAREED ZAKARIA, THE POST-AMERICAN WORLD 133 (2008) (making a similar observation regarding India: "[India] might have several Silicon Valleys, but it also has three Nigerias within it—that is, more than 300 million people living on less than a dollar a day.").

135. CNIPA, *Domestic Applications and Applications for Three Kinds of Patents*, http://www.cnipa.gov.cn/tjxx/jianbao/year2018/a/a4.html (last visited July 31, 2019) [hereinafter CNIPA, *Domestic Applications*] (on file with *The University of the Pacific Law Review*).

136. *Id*.

137. CNIPA, *Domestic Grants for Three Kinds of Patents*, http://www.cnipa.gov.cn/tjxx/jianbao/year2018/b/b3.html (last visited July 31, 2019) [hereinafter CNIPA, *Domestic Grants*] (on file with *The University of the Pacific Law Review*).

138. *Id*.

139. CNIPA, *Domestic Applications*, *supra* note 135; CNIPA, *Domestic Grants*, *supra* note 137.

140. As I noted in a recent article:

> From the standpoint of intellectual property development, having highly uneven subnational development could create major challenges for policymakers, especially in relation to the establishment of a national intellectual property strategy, such as the one the State Council of China launched in June 2008. If the relevant government leaders seek to tailor protection to the divergent economic and technological conditions in different regions, they likely will have to come up with a "schizophrenic" nationwide intellectual property policy. Under such a policy, protection will be tighter in fast-growing and technologically proficient regions but much weaker in their less-

works in another. Moreover, because different sectors in China develop at different paces, the need for schizophrenic policies can be attributed to not only regional disparities, but also sectoral disparities. As I noted a decade ago, before the State Council's adoption of the National Intellectual Property Strategy, "based on existing developments, China is likely to prefer stronger protection of intellectual property rights in entertainment, software, semiconductors, and selected areas of biotechnology to increased protection in areas concerning pharmaceuticals, chemicals, fertilizers, seeds, and foodstuffs."[141]

From a public health standpoint, the uneven economic and technological developments in China have also been highly alarming. As China increases its assertiveness in the pharmaceutical arena and as the pharmaceutical landscape continues to evolve, one cannot help but wonder whether and how China's eagerness to develop national champions in this arena will affect the overall access of the Chinese populace to medicines and healthcare. As Frederick Abbott rightly reminded us:

> [I]n order for the health sector not to be adversely affected, there must be some type of transfer payment, whether in the form of increased public health expenditures on pharmaceuticals, by providing health insurance benefits, or other affirmative acts. In a world of economic scarcity, the prospect that governments will act to offset increases in medicines prices with increased public health expenditures is uncertain.[142]

To be sure, innovation and intellectual property policies remain key components of the larger public health policy. If stronger intellectual property rights are created, such protections can be balanced by greater limitations and exceptions to these rights, as well as by introducing competition law, other legal or policy safeguards, or complementary public health measures.[143] Nevertheless,

---

developed counterparts.

Yu, *Spatial Critique*, *supra* note 129, at 2096 (footnotes omitted); *see also* Yu, *Regime Complex*, *supra* note 131, at 24–25 (explaining why the intellectual property developments in China should not be analyzed as if the country were homogeneous).

141. Yu, *Regime Complex*, *supra* note 131, at 25.

142. Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 27, 33 (Pedro Roffe et al. eds., 2006).

143. *See* Eric Ng, *China Pharma Must Swallow That Jagged Little Pill Called R&D as Government Slashes Profit Margins of Generic Drugs*, S. CHINA MORNING POST (Jan. 19, 2019), https://www.scmp.com/business/companies/article/2182740/china-pharma-must-swallow-jagged-little-pill-called-rd-government (on file with *The University of the Pacific Law Review*) (reporting "Beijing's recent pilot roll-out of state hospital bulk purchase open bidding" and that "the first round of price bidding in 11 cities saw prices slashed by 62 per cent on average"). Included in this centralized medicine procurement scheme were Beijing, Chengdu, Chongqing, Dalian, Guangzhou, Shanghai, Shenyang, Shenzhen, Tianjin, Xi'an, and Xiamen. Press Release, The State Council of the People's Republic of China, State Council Approves Centralized Medicine Procurement (Jan. 17, 2019), http://english.www.gov.cn/policies/latest_releases/2019/01/17/content_281476482971182.htm (on file with *The University of the Pacific Law Review*).

as we have seen in many parts of the world—especially in developing countries—the development of a strong patent system often results in a lower quality of healthcare for those who cannot afford high-priced drugs.[144] Even if there is hope that China will eventually find a way to create a more balanced healthcare system amid its effort to create national champions in the pharmaceutical arena,[145] there are very few, if any, historical examples for China to use as reference points. The continuous public concern about inadequate or unaffordable healthcare indeed explained why the film *Dying to Survive* resonated with tens of millions in China and became a local blockbuster.[146] Policymakers and commentators should not overlook the costs of creating national pharmaceutical champions.

A related area that also deserves policy and scholarly attention concerns the impact of the recent law and policy changes on the future development of traditional Chinese medicine,[147] which in 2015 "account[ed] for 28.55% of the total [output value] generated by the country's pharmaceutical industry."[148]

144. *See generally* COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 29–55 (2002) (discussing issues lying at the intersection of intellectual property, development, and public health).

145. As Frederick Abbott observed in a World Health Organization study: "[T]he single most important aspect of China's current policy with respect to the pharmaceutical sector is its close linkage to the objective of universal health care (UHC). UHC is a key priority for the China Government, which has committed to providing access to medicines for its people." WHO CHINA STUDY, *supra* note 1, at 1; *see also id*. at 6–7 (discussing China's commitment to universal health care).

146. DYING TO SURVIVE [WO BU SHI YAOSHEN] (Dirty Monkey Films Group 2018); *see also Chinese Box Office for 2018*, BOX OFFICE MOJO, https://www.boxofficemojo.com/year/2018/?area=CN&ref_=bo_yl_table_3 (last visited Apr. 13, 2020) (on file with *The University of the Pacific Law Review*) (providing statistics on the film's phenomenal success in the Chinese box office). *Wo bu shi yaoshen* translates to "I am not God of Medicine." Based on a real-life story, the film concerned the owner of a Chinese aphrodisiac store who smuggled cheap generic medicine from India for sale at affordable prices to leukemia patients in China.

147. As Fan Ruiping explained:

> Traditional Chinese medicine dramatically differs from modern scientific medicine in its basic medical orientation, physiological theories, etiology, diagnostics, therapeutics, and pharmacology. For instance, while modern scientific medicine views the essence of illness as anatomicopathological, traditional Chinese medicine views it as symptom-complex (*zheng*) of the whole body. While scientific medicine identifies the sources of illness as disease entities, Chinese medicine identifies them as imbalanced climate and/or emotional factors. While scientific medicine uses advanced lab and mechanical investigations as diagnostic means, Chinese medicine uses ordinary contacts (looking, smelling, asking, and feeling) to locate problems. While scientific medicine emphasizes pathological anatomy, Chinese medicine focuses on the patient's complaint and actual experience of being sick. While scientific medicine aims at curing diseases, Chinese medicine appeals to balancing functional factors. While scientific medicine employs chemical drugs or surgeries, Chinese medicine appeals to natural herbs or simple needles.

Fan Ruiping, *Modern Western Science as a Standard for Traditional Chinese Medicine: A Critical Appraisal*, 31 J.L. MED. & ETHICS 213, 213 (2003); *see also* WHO CHINA STUDY, *supra* note 1, at 21–22 (discussing the development of traditional Chinese medicines in China).

148. WHO, WHO GLOBAL REPORT ON TRADITIONAL AND COMPLEMENTARY MEDICINE 2019, at 164 (2019) [hereinafter WHO TRADITIONAL MEDICINE REPORT]. As the World Health Organization stated in its latest report on traditional and complementary medicines:

> As at end 2017, more than 60 000 traditional Chinese medicines and ethnic minority medicines have

Although English-language discussions of intellectual property protections for traditional Chinese medicines and the related challenges remain limited,[149] a sizeable portion of the Chinese population still relies heavily on this type of medicine, or a combination of both Western and Chinese medicines.[150] Thus, in view of China's growing assertiveness in the pharmaceutical arena, it is fair to ask how such assertiveness will affect the future development of traditional Chinese medicine. Will the greater development of Western medicine and national champions that specialize in the development of such medicine lead to more innovation of traditional Chinese medicine?[151] More integration?[152] More

---

> been approved (based on the number of Approval Letters), and 4424 pharmaceutical enterprises (including active pharmaceutical ingredient and finished dosage forms) have been granted manufacturing licences and passed the [good manufacturing practice] inspection. In addition, 177 sites for crude drugs (raw pharmaceutical materials) have been certified for good agricultural practices (GAP). Chinese drug regulatory authorities are also exploring the revision of GAP and the implementation of a record system for Chinese crude drugs. A modern Chinese pharmaceutical industry, held together by commerce, has been established. In 2015, the total output value of the traditional Chinese medicine pharmaceutical industry was RMB 786.6 billion, accounting for 28.55% of the total generated by the country's pharmaceutical industry.

Id.

149. For discussions of the protection for traditional Chinese medicines and related challenges, see generally LI, *supra* note 110, at 35–36; Jerry I.H. Hsiao, *Patent Protection for Chinese Herbal Medicine Product Invention in Taiwan*, 10 J. WORLD INTELL. PROP. 1 (2007); Li Xuan & Li Weiwei, *Inadequacy of Patent Regime on Traditional Medicinal Knowledge—A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China*, 10 J. WORLD INTELL. PROP. 125 (2007); Lin Peng, *Striking a Balance Between Intellectual Property Protection of Traditional Chinese Medicine and Access to Knowledge*, 7 TSINGHUA CHINA L. REV. 271 (2015); Zhang Dong, *Observations from a TRIPS Perspective: Do We Need a Traditional Medicine Exemption for Patent Standards*, 13 OR. REV. INT'L L. 305 (2011); Zhuo Jing, *Legal Protection of Traditional Chinese Medicine in the Context of the Creative Economy*, 47 HONG KONG L.J. 171 (2017); Benjamin Liu, Comment, *Past Cultural Achievement as a Future Technological Resource: Contradictions and Opportunities in the Intellectual Property Protection of Chinese Medicine in China*, 21 UCLA PAC. BASIN L.J. 75 (2003).

150. As the World Health Organization stated in its report:

> At the end of 2015, there were 3966 traditional Chinese medicine hospitals across the country, including 253 hospitals of ethnic minority medicine and 446 hospitals of integrated Chinese and Western medicine; there were 452 000 practitioners and assistant practitioners of traditional Chinese medicine (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine); there were 42 528 traditional Chinese medicine clinics, including 550 for ethnic minority medicine and 7706 for integrated medicine; there were 910 million visits that year to traditional Chinese medicine medical and health service units across the country and 26 915 000 in-patients treated.

WHO TRADITIONAL MEDICINE REPORT, *supra* note 148, at 164; *see also* Fan, *supra* note 147, at 214–16 (documenting the prosperous development of traditional Chinese medicines and medical practices in China while lamenting that the monostandard used in the integrated Chinese health care system).

151. *See* Zhuo, *supra* note 149, at 177 ("Science, technology and innovation are . . . indispensable elements for the advancement of the pharmaceutical industry, and in particular the [traditional Chinese medicine] industry in China . . . .").

152. *See* WHO TRADITIONAL MEDICINE REPORT, *supra* note 148, at 164 ("The state encourages exchanges between traditional Chinese medicine and Western medicine, and creates opportunities for Western medical practitioners to learn from their traditional Chinese medicine counterparts."); Zhuo, *supra* note 149, at 179 ("[S]cience, technology and innovation have . . . increased the combined applications of [traditional Chinese medicine] and western medicine.").

co-evolution? More displacement? Or more weakening? What impact, if any, such development will have on the Chinese populace?

C. Global Complications

The final area that deserves greater attention pertains to the global complications China's changing position in the pharmaceutical arena has generated. Since entering the WTO in December 2001, China has joined Brazil and India in pushing for stronger accommodation of developing countries' interests in the international trading and intellectual property systems.[153] Together with Russia and South Africa, these three countries have worked hard to explore greater cooperation in the BRICS context.[154]

Ironically, China's recent policy shift in the pharmaceutical arena will create tensions, if not conflicts, with India.[155] While India remains eager to provide strong support for generic drugs at the international level[156]—notwithstanding the changing dynamics in its pharmaceutical industry[157]—China's position is now

153. *See* Peter K. Yu, *Intellectual Property Negotiations, the BRICS Factor and the Changing North–South Debate*, *in* THE BRICS-LAWYERS' GUIDE TO GLOBAL COOPERATION 148, 149 (Rostam J. Neuwirth et al. eds., 2017) [hereinafter Yu, *BRICS Factor*] ("Having acceded to the World Trade Organization . . . in December 2001, China has now joined Brazil and India—the two longtime leaders of the developing world—in pushing for their preferred international trade and intellectual property norms."); Yu, *Access to Medicines*, *supra* note 1, at 358–62 (arguing that, if Brazil, China, and India are willing to team up with each other, they could form a formidable alliance that could rival the traditional trilateral alliance among the European Union, Japan, and the United States); Yu, *Virotech Patents*, *supra* note 23, at 1645 ("Whether the debate is about access to essential medicines or the protection of genetic materials in viruses, less developed countries have played a very important role. Of particular importance are the policy positions taken by leaders of this group: Brazil, China, and India.").

154. "BRICS" refers to Brazil, Russia, India, China, and South Africa. *See* Yu, *Half-Century of Scholarship*, *supra* note 51, at 1116 (noting the past BRICS summits); *see also* Yu, *BRICS Factor*, *supra* note 153 (discussing the "BRICS factor" in international trade and intellectual property negotiations).

155. *Cf.* WHO CHINA STUDY, *supra* note 1, at 17 ("China . . . appears to have displaced India as the largest API exporter, and Chinese API producers supply a good part of the Indian market." (footnote omitted)); WHO, INDIAN POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 33 (2017), https://www.who.int/phi/publications/2081India020517.pdf (prepared by Frederick Abbott) (on file with *The University of the Pacific Law Review*) ("India and China are major competitors in the pharmaceutical sector, and that competition is likely to intensify.").

156. As my colleague Srividhya Ragavan declared emphatically:

> [D]ata exclusivity as a tool detrimentally affects generic competition. Thus, it is no coincidence that India has been pressurized by the [United States Trade Representative] to extend the existing 4 year period of data exclusivity to 10 years. For countries like India, it is good to appreciate that generics have become a part of the global pharmaceutical industry.

Srividhya Ragavan, *Data Exclusivity: A Tool to Sustain Market Monopoly*, 8 JINDAL GLOBAL L. REV. 241, 260 (2017) (footnote omitted); *see also* Ragavan, *(Re)Newed Barrier*, *supra* note 79, at 1188 (discussing the four years of data exclusivity protection provided by Section 122E of the Indian Drugs and Cosmetics Act of 1940); Srividhya Ragavan, *The Significance of the Data Exclusivity and Its Impact on Generic Drugs*, 1 J. INTELL. PROP. STUD. 131, 140 (2017) (arguing that "India has a perfectly fine data exclusivity provision" and does not need to strengthen protection in this area); Prashant Reddy T., *The Data Exclusivity Debate in India: Time for a Rethink?*, 10 INDIAN J.L. & TECH. 8, 17–25 (2014) (capturing the debate in India on the protection of undisclosed test or other data for pharmaceutical and agrochemical products).

157. *See* Sudip Chaudhuri, *Is Product Patent Protection Necessary to Spur Innovation in Developing*

closer to those of the European Union, Japan, Switzerland, the United States, and other developed countries.[158] This position shift has raised questions about the ongoing negotiations at the WTO and WIPO. Will both China and India continue to team up to push for standards that align with the positions of developing countries? Or will the slowly changing pharmaceutical landscape cause these two leaders of the developing world to slowly drift apart? If so, how can other developing countries maintain an effective coalition to push for positions that are more in line with their needs, interests, conditions, and priorities?

Although the multilateral system involving the WTO and WIPO has received considerable scholarly and policy attention, the biggest tensions between China and India over the development of regulatory standards in the pharmaceutical arena will likely arise at the regional level.[159] A case in point is the ongoing negotiation of the Regional Comprehensive Economic Partnership ("RCEP"),[160] in which both China and India have played important roles.[161] While the draft RCEP intellectual property chapter has never been officially released, Knowledge Ecology International—a nongovernmental organization active in the health and intellectual property arenas—leaked online the October 15, 2015

Countries?: R&D by Indian Pharmaceutical Companies After TRIPS, *in* THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES 265, 285–86 (Neil Weinstock Netanel ed., 2009) (discussing new drug-delivery systems in India); Dwijen Rangnekar, *Context and Ambiguity in the Making of Law: A Comment on Amending India's Patent Act*, 10 J. WORLD INTELL. PROP. 365, 379–80 (2007) (noting the changing configuration of Indian pharmaceutical firms); Yu, *Access to Medicines*, *supra* note 1, at 390–91 (noting the dynamic development of the pharmaceutical sector in the BRICS countries).

158. *See supra* Part III (discussing the changing pharmaceutical landscape in China).

159. *See generally* Peter K. Yu, *The RCEP Negotiations and Asian Intellectual Property Norm Setters*, *in* THE FUTURE OF ASIAN TRADE DEALS AND IP 85 (Liu Kung-Chung & Julien Chaisse eds., 2019) [hereinafter Yu, *Norm Setters*] (discussing the rivalry between Asian intellectual property norm setters in the context of the RCEP negotiations); Anupam Chander & Madhavi Sunder, *The Battle to Define Asia's Intellectual Property Law: From TPP to RCEP*, 8 U.C. IRVINE L. REV. 331 (2018) (discussing the struggle between key RCEP negotiating parties over intellectual property rules).

160. The RCEP negotiations have involved Australia, China, India, Japan, New Zealand, South Korea, and the Association of Southeast Asian Nations (ASEAN). *See* ASEAN Plus Six, Joint Declaration on the Launch of Negotiations for the Regional Comprehensive Economic Partnership (Nov. 20, 2012), https://dfat.gov.au/trade/agreements/negotiations/rcep/news/Documents/joint-declaration-on-the-launch-of-negotiations-for-the-regional-comprehensive-economic-partnership.pdf (on file with *The University of the Pacific Law Review*) (launching the RCEP negotiations). In November 2019, India withdrew from the RCEP negotiations. *See* Niranjan Marjani, *India Had Good Reason to Pull Out of RCEP*, DIPLOMAT (Nov. 5, 2019), https://thediplomat.com/2019/11/india-had-good-reason-to-pull-out-of-rcep/ (on file with *The University of the Pacific Law Review*). Despite India's lack of involvement in the latest negotiation efforts, nothing precludes the country from rejoining the negotiations. *See* Kunal Purohit, *India's "Door Still Open" to RCEP Free-Trade Deal: Foreign Minister Subrahmanyam Jaishankar*, S. CHINA MORNING POST (Jan. 15, 2020, 7:30 PM), https://www.scmp.com/week-asia/politics/article/3046231/indias-door-still-open-rcep-free-trade-deal-foreign-minister (on file with *The University of the Pacific Law Review*).

161. For the Author's analysis of the RCEP, see generally Yu, *Norm Setters*, *supra* note 159; Peter K. Yu, *TPP, RCEP, and the Crossvergence of Asian Intellectual Property Standards*, *in* GOVERNING SCIENCE AND TECHNOLOGY UNDER THE INTERNATIONAL ECONOMIC ORDER: REGULATORY DIVERGENCE AND CONVERGENCE IN THE AGE OF MEGAREGIONALS 277 (Peng Shin-yi et al. eds., 2018); Peter K. Yu, *TPP, RCEP and the Future of Copyright Norm-setting in the Asian Pacific*, *in* MAKING COPYRIGHT WORK FOR THE ASIAN PACIFIC: JUXTAPOSING HARMONISATION WITH FLEXIBILITY 19 (Susan Corbett & Jessica C. Lai eds., 2018); Yu, *RCEP and Trans-Pacific Norms*, *supra* note 89.

version of that chapter.[162] This draft chapter included a provision that requires "no less than five years" of protection to undisclosed test or other data submitted for the regulatory approval of pharmaceutical products.[163] On that draft, the language for a six-year term, which is in line with China's WTO commitment,[164] was specifically crossed out.[165] In addition, that draft declined to offer protection to biological products, providing a significant contrast with Article 18.51 of the TPP Agreement.[166]

Thus, if in the near future China switched its position in the RCEP negotiations to push for stronger protections for pharmaceutical and biological products—a new position that is consistent with the recently proposed amendments to Chinese patent law and pharmaceutical regulations[167]—India and a few ASEAN members would become the lone holdouts within the sixteen RCEP negotiating parties. As the leaked draft text revealed, Japan and South Korea were the negotiating parties proposing the data exclusivity provision.[168] Although Australia and New Zealand opposed such protection, both Australia and New Zealand signed the TPP Agreement, suggesting their willingness to accept high TPP-like standards for the protection of pharmaceutical and biological products.[169] If these three countries were to eventually join those ASEAN members that have embraced stronger intellectual property protection and enforcement, such as Singapore, China's changing position will have serious ramifications for future international and regional intellectual property negotiations.

Finally, since fall 2013, China has been actively pushing for the development

---

162. Regional Comprehensive Economic Partnership Intellectual Property Chapter (Oct. 15 draft), http://keionline.org/sites/default/files/RCEP-IP-Chapter-15October2015.docx [hereinafter October 15 Draft] (on file with *The University of the Pacific Law Review*); *see also* James Love, *2015 Oct 15 Version: RCEP IP Chapter*, KNOWLEDGE ECOLOGY INT'L (Apr. 19, 2016), http://keionline.org/node/2472 (on file with *The University of the Pacific Law Review*) (providing the leaked text).

163. October 15 Draft, *supra* note 162, art. 5.16.

164. *WTO Accession Report*, *supra* note 77, ¶ 284.

165. October 15 Draft, *supra* note 162, art. 5.16.

166. *Compare id*. *with* TPP Agreement, *supra* note 93, art. 18.51; *see also* Yu, *Data Exclusivities*, *supra* note 78, at 680 ("[T]he draft RCEP chapter does not include any provision on biologics. The omission is understandable considering the deep controversy surrounding the provision on biologics that arose toward the end of the TPP negotiations.").

167. *See supra* notes 74–85 (discussing the amendments).

168. October 15 Draft, *supra* note 162, art. 5.16.

169. Both Australia and New Zealand signed the TPP Agreement even though it offered at least eight years of protection to undisclosed test or other data submitted for the regulatory approval of biological products. *See* Press Release, Office of the U.S. Trade Representative, Trans-Pacific Partnership Ministers' Statement (Feb. 4, 2016), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/February/TPP-Ministers-Statement (on file with *The University of the Pacific Law Review*) (reporting the signing of the TPP Agreement in Auckland, New Zealand in February 2016). In November 2016, New Zealand also passed the requisite bill to ratify the Agreement. *See TPP Bill Signed by Parliament as US Signals Its End*, RADIO N.Z. (Nov. 15, 2016), http://www.radionz.co.nz/news/political/318141/tpp-bill-signed-byparliament-as-us-signals-its-end (on file with *The University of the Pacific Law Review*).

of the Belt and Road Initiative ("BRI").[170] Although this initiative has thus far focused on interconnectivity and infrastructural developments,[171] there has been growing developments in the intellectual property area.[172] At the time of writing, China has already hosted two high-level international conferences on BRI-related intellectual property matters.[173] In May 2017, the country also entered into the Agreement on Enhancing "Belt and Road" Intellectual Property Cooperation with WIPO.[174] In addition, "over the past [few] years, China has carried out extensive cooperation with [Belt and Road] countries in terms of [intellectual property] education, publicity, training and information exchange."[175] Given the important role the BRI can play in facilitating intellectual property cooperation,[176] China's position in the pharmaceutical arena will likely have serious ramifications for future intellectual property developments in the more than sixty countries along the Belt and Road.

---

170. *See* NAT'L DEV. & REFORM COMM'N ET AL., VISION AND ACTIONS ON JOINTLY BUILDING SILK ROAD ECONOMIC BELT AND 21ST-CENTURY MARITIME SILK ROAD (2015) (providing the official translation of a guiding document for the development of this initiative).

171. *See* DAVID SHAMBAUGH, CHINA'S FUTURE 162–63 (2016) ("[The BRI sought] to build infrastructure and facilitate commercial 'connectivity' from northwestern China across Eurasia and from southeast China to Africa and the eastern Mediterranean. Through [this and other] initiatives, China is meticulously constructing an alternative and parallel global institutional architecture to the postwar western order.").

172. For discussions of the BRI in the intellectual property context, see generally Lee Jyh-an, *The New Silk Road to Global IP Landscape*, *in* LEGAL DIMENSIONS OF CHINA'S BELT AND ROAD INITIATIVE 417 (Lutz-Christian Wolff & Xi Chao eds., 2016); Peter K. Yu, *Building Intellectual Property Infrastructure Along China's Belt and Road*, 14 U. PA. ASIAN L. REV. 281 (2019) [hereinafter Yu, *Building IP Infrastructure*]; Peter K. Yu, *China, "Belt and Road" and Intellectual Property Cooperation*, 14 GLOBAL TRADE & CUSTOMS J. 244 (2019).

173. *See* Press Release, CNIPA, The 2018 High-Level Conference on IP for Countries Along Belt and Road Highlights Inclusiveness, Development, Cooperation, Mutual Benefit (Aug. 29, 2018), http://english.cnipa.gov.cn/specialtopic/tbar2018/tbar2018headlines/1131331.htm (on file with *The University of the Pacific Law Review*) (recounting the 2016 conference); Press Release, WIPO, High Level "Belt and Road" Conference Urges Closer IP Collaboration for Economic Growth (July 27, 2016), http://www.wipo.int/about-wipo/en/offices/china/news/2016/news_0008.html (on file with *The University of the Pacific Law Review*) (recounting the 2016 conference).

174. Press Release, WIPO Director General Visits Belt and Road Forum and China Supreme People's Court (May 18, 2017), https://www.wipo.int/about-wipo/en/offices/china/news/2017/news_0001.html (on file with *The University of the Pacific Law Review*).

175. Li You, *Intellectual Property in Focus at High-Level Forum in Beijing*, CHINA DAILY (Aug. 29, 2018), http://www.chinadaily.com.cn/cndy/2018-08/29/content_36837702.htm (on file with *The University of the Pacific Law Review*); *see also id*. ("In the past two years, China . . . signed memorandums of understanding on [intellectual property] cooperation with a large number of countries including Tajikistan, Vietnam, Laos, the Philippines, Bangladesh, Kyrgyzstan, Kazakhstan, Armenia, Albania, Bulgaria, Latvia, Lithuania and Egypt.").

176. In past scholarship, I explored how the BRI can promote intellectual property cooperation in six distinct areas: "substantive standards, procedural arrangements, cross-border enforcement, dispute resolution, technical cooperation, and market aggregation." Yu, *Building IP Infrastructure*, *supra* note 172, at 278; *see also id*. at 301–22 (discussing cooperation in these areas).

V. CONCLUSION

In the past three decades, China has been slowly but actively building its patent system. Having undergone multiple developmental phases—from imitation to standardization to integration to indigenization[177]—the Chinese patent system has arguably advanced much faster than any system that has ever been built.[178] In the past few years, China has also been actively strengthening its position in the pharmaceutical arena. While the proposed changes to patent law and pharmaceutical regulations provide good indications of what is to come in the near future, China's growing deployment of artificial intelligence and machine learning in the health area also deserves scholarly and policy attention. Given all of these developments, it is high time that policymakers and commentators paid greater attention to China's assertiveness in the pharmaceutical arena and the changing domestic and global pharmaceutical landscapes. Until policymakers and commentators foster a deeper understanding of these changes and developments, they will have great difficulty formulating appropriate regulatory and policy responses toward China.

177. *See* Yu, *Half-Century of Scholarship*, *supra* note 51, at 1058–87 (discussing these four phases of "imitation and transplantation," "standardization and customization," "integration and assimilation," and "indigenization and transformation").

178. *See* Yu, *Building the Ladder*, *supra* note 14, at 2 ("China . . . has accomplished what no other country has ever achieved in such a short period of time—be it Germany, Japan or the United States. While it took the now-developed countries centuries to establish their patent systems, the same feat took China only three decades."); Peter K. Yu, *Trade Secret Hacking, Online Data Breaches, and China's Cyberthreats*, 2015 CARDOZO L. REV. DE NOVO 130, 139 (noting that China "has built a new intellectual property system from the ground up faster than any other country in history").