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## Vaccine Development, the China Dilemma, and International Regulatory Challenges

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VACCINE DEVELOPMENT, THE CHINA DILEMMA,  
AND INTERNATIONAL REGULATORY  
CHALLENGES

PETER K. YU\*

*This article examines the role played by China in the development of international regulatory standards at the intersection of intellectual property, international trade, and public health. It begins by briefly discussing the role China has played in the global health arena during the COVID-19 pandemic. The article then highlights the difficulty in determining how best to engage with the country in the development of new international regulatory standards. It shows that the preferred method of engagement will likely depend on one's perspective on China's potential contributions and hindrances: a perspective that focuses on global competition—in the economic, trade, and technological arenas—is likely to differ significantly from one emphasizing global health. This article concludes by providing four key takeaways concerning the challenges and complications that China has posed, or will pose, to policymakers in the development of new international regulatory standards.*

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## I. INTRODUCTION

Since the World Health Organization (WHO) declared COVID-19 a global pandemic in March 2020,<sup>1</sup> countries, intergovernmental bodies, nongovernmental organizations, and individual experts have called for the development of new global frameworks and adjustments to international regulatory standards. Among the proposals that have received considerable attention are amendments to the International Health Regulations,<sup>2</sup> efforts to create an international treaty on pandemics under the WHO's auspices,<sup>3</sup> and an unprecedented proposal at the World Trade Organization (WTO) to temporarily waive about half of the provisions of the Agreement on Trade-Re-

1. *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19—11 March 2020*, WORLD HEALTH ORG. (Mar. 11, 2020), <https://www.who.int/director-general/speeches/detail/who-director-general-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020> [https://perma.cc/K2ZJ-LJ8J].

2. *See, e.g.*, Strengthening WHO Preparedness for and Response to Health Emergencies Proposal for Amendments to the International Health Regulations (2005), WHO Doc. A75/A/CONF./7 Rev.1 (May 27, 2022) (providing a draft resolution advanced by Australia, Bosnia and Herzegovina, Colombia, the European Union, Japan, Monaco, South Korea, the United Kingdom, and the United States).

3. For discussions of the proposed WHO instrument on pandemic prevention, preparedness, and response, see generally Fernando dos Santos et al., *Intellectual Property Framework Responses to Health Emergencies—Options for Africa*, 118 S. AFR. J. SCI. 12775, at 4 (2022), <https://sajs.co.za/article/view/12775>; Obijiofor Aginam, *The Proposed Pandemic Treaty and the Challenge of the South for a Robust Diplomacy* (S. Ctr., SouthViews No. 218, 2021), <https://www.southcentre.int/southviews-no-218-19-may-2021/> [https://perma.cc/NR5B-4GBV]; Germán Velásquez & Nirmalya Syam, *A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?* (S. Ctr., Policy Brief No. 93, 2021), <https://www.southcentre.int/wp-content/uploads/2021/05/SouthViews-Aginam.pdf> [https://perma.cc/7L2D-BEJW].

lated Aspects of Intellectual Property Rights (TRIPS or TRIPS Agreement)<sup>4</sup> to facilitate the “prevention, containment or treatment of COVID-19” (COVID-19 TRIPS waiver).<sup>5</sup>

As the pandemic has slowly evolved into an endemic—at least in the Global North<sup>6</sup>—demands for emergency relief measures have given way to debates on the development of new international regulatory standards to provide a more effective response during the inter-pandemic period and in the post-COVID-19 era.<sup>7</sup> One challenging and inevitable debate concerns the role played by China in the development of international regulatory standards at the intersection of intellectual property, international trade, and public health.<sup>8</sup> Among the important issues are whether China will support the development of new standards, whether its participation will create complications, how and how fast its role will evolve in the near future, and how other countries should engage with China in

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4. 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].

5. Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter *TRIPS Waiver Proposal*]; Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021) [hereinafter *Revised TRIPS Waiver Proposal*].

6. See Lara Herrero & Eugene Madzokere, *COVID Will Likely Shift from Pandemic to Endemic—but What Does That Mean?*, THE CONVERSATION (Sept. 20, 2021, 2:45 AM), <https://theconversation.com/covid-will-likely-shift-from-pandemic-to-endemic-but-what-does-that-mean-167782> [<https://perma.cc/P88E-66EG>] (discussing the shift of COVID-19 from a pandemic to an endemic); Nicky Phillips, *The Coronavirus Is Here to Stay—Here’s What That Means*, NATURE (Feb. 16, 2021), <https://www.nature.com/articles/d41586-021-00396-2> [<https://perma.cc/PR3K-YWD2>] (explaining what it means for COVID-19 to stay as an endemic).

7. See *supra* text accompanying notes 2–3 (discussing the efforts to amend the International Health Regulations and create an international treaty on pandemics).

8. For the Author’s earlier work on this debate, see generally Peter K. Yu, *China, the TRIPS Waiver and the Global Pandemic Response*, in INTELLECTUAL PROPERTY, COVID-19, AND THE NEXT PANDEMIC: DIAGNOSING PROBLEMS, DEVELOPING CURES (Madhavi Sunder & Sun Haochen eds., forthcoming 2023) [hereinafter Yu, *China, the TRIPS Waiver*]; Peter K. Yu, *China’s Innovative Turn and the Changing Pharmaceutical Landscape*, 51 U. PAC. L. REV. 593 (2020) [hereinafter Yu, *China’s Innovative Turn*].

the international regulatory system. Improving global pandemic preparedness in this system is particularly important considering that many medical and public health experts have already predicted that another global pandemic will emerge in the next decade or two.<sup>9</sup>

Part II of this Article briefly discusses the role China has played in the global health arena during the COVID-19 pandemic. Part III highlights the difficulty in determining how best to engage with the country in the development of new international regulatory standards. This Part shows that the preferred method of engagement will likely depend on one's perspective on China's potential contributions and hindrances: a perspective that focuses on global competition—in the economic, trade, and technological arenas—is likely to differ significantly from one emphasizing global health. Part IV concludes by providing four key takeaways concerning the challenges and complications that China has posed, or will pose, to policymakers in the development of new international regulatory standards.

## II. CHINA'S CHANGING ROLE IN GLOBAL HEALTH

As far as COVID-19 vaccines are concerned, AstraZeneca, Moderna, Pfizer–BioNTech, and Johnson & Johnson have received considerable attention.<sup>10</sup> These vaccines are noted for the use of novel technology, such as mRNA or adenovirus. By contrast, the vaccines developed in China—notably those by Sinopharm and Sinovac—relied on an inactivated SARS-CoV-2 virus.<sup>11</sup> Such reliance has attracted questions about the vac-

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9. See, e.g., STEFAN ELBE, PANDEMICS, PILLS, AND POLITICS: GOVERNING GLOBAL HEALTH SECURITY 34 (2018) (“The episodic recurrence of . . . influenza pandemics leads many experts to believe that new flu pandemics occur roughly once every couple of decades.”); SONIA SHAH, PANDEMIC: TRACKING CONTAGIONS, FROM CHOLERA TO EBOLA AND BEYOND 8 (2016) (noting a survey by epidemiologist Larry Brilliant that concluded “90 percent of epidemiologists said that a pandemic that will sicken 1 billion, kill up to 165 million, and trigger a global recession that could cost up to \$3 trillion would occur sometime in the next two generations”).

10. Julia Hollingsworth et al., *Why Covid-19 Outbreaks in Countries Using Chinese Vaccines Don't Necessarily Mean the Shots Have Failed*, CNN (July 3, 2021), <https://edition.cnn.com/2021/07/02/china/vaccines-sinovac-sinopharm-intl-hnk-dst/index.html> [https://perma.cc/TS9R-ZBWM].

11. *Id.*

cines' efficacy.<sup>12</sup> Notwithstanding their use of more dated technology, Chinese vaccine manufacturers have also been actively developing mRNA vaccines. The patent landscape report published by the World Intellectual Property Organization (WIPO) on COVID-19-related vaccines and therapeutics indicated that, by fall 2021, two Chinese RNA-based vaccines had reached Phase 1 or Phase 3 trials.<sup>13</sup> In September 2022, Indonesia granted emergency use approval of one of these vaccines—AWcorna (formerly ARCoV), an mRNA vaccine developed by Walvax Biotechnology, Suzhou Abogen Biosciences, and the Academy of Military Science.<sup>14</sup>

The progress Chinese vaccine manufacturers have been making toward the development of mRNA vaccines has sparked concerns among foreign vaccine manufacturers and their supportive governments. For instance, in spring 2021, when WTO members were debating heatedly about whether to adopt the COVID-19 TRIPS waiver proposed by India and South Africa,<sup>15</sup> some pharmaceutical companies went out of their way to stress that a broad waiver would lead to the involuntary transfer of cutting-edge mRNA technology to China and Russia.<sup>16</sup> While the industry worries undoubtedly reso-

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12. *See id.* (noting questions and concerns about the lower efficacy of Chinese vaccines). From a public health standpoint, these vaccines are still efficacious and have helped combat COVID-19.

13. WORLD INTELL. PROP. ORG., COVID-19-RELATED VACCINES AND THERAPEUTICS: PRELIMINARY INSIGHTS ON RELATED PATENTING ACTIVITY DURING THE PANDEMIC 61–62 (2022).

14. Stanley Widiyanto & Roxanne Liu, *A Chinese mRNA COVID Vaccine Is Approved for the First Time—in Indonesia*, REUTERS (Sept. 30, 2022, 8:30 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/indonesia-drug-agency-approves-chinas-walvax-mrna-vaccine-emergency-use-2022-09-29/> [<https://perma.cc/3ZGB-XRRV>].

15. *TRIPS Waiver Proposal*, *supra* note 5; *Revised TRIPS Waiver Proposal*, *supra* note 5.

16. *See* Hannah Kuchler & Aime Williams, *Vaccine Makers Say IP Waiver Could Hand Technology to China and Russia*, FIN. TIMES (Apr. 25, 2021), <https://www.ft.com/content/fa1e0d22-71f2-401f-9971-fa27313570ab> [<https://perma.cc/7TZB-QHX9>] (“As industry lobbying has escalated in Washington, companies have warned in private meetings with US trade and White House officials that giving up the intellectual property rights could allow China and Russia to exploit platforms such as mRNA, which could be used for other vaccines or even therapeutics for conditions such as cancer and heart problems in the future.”); D. Ravi Kanth, *Big Pharma to Block TRIPS Waiver at WTO, Citing China & Russia*, TWN INFO SERV. ON WTO & TRADE ISSUES (Apr. 27, 2021), <https://www.twn.my/title2/wto.info/2021/ti210415.htm> [<https://>

nated with the concerns of U.S. politicians, policymakers, and commentators about U.S.-China economic and technological rivalry,<sup>17</sup> the fact that China now has mRNA vaccine technology certainly explains why U.S. and other vaccine manufacturers fear that they would lose their global competitive edge.

Since the beginning of the COVID-19 pandemic, China has distributed more than a billion doses of vaccines to over 100 countries.<sup>18</sup> Despite the oft-noted concern that Chinese vaccines may be of lower efficacy,<sup>19</sup> many countries, especially those in the developing world, are willing to accept conventional vaccines due to their reduced costs and ease of storage.<sup>20</sup> In May and June 2021, the WHO validated Sinopharm

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[/perma.cc/E4CB-AJ9Y](https://perma.cc/E4CB-AJ9Y)) (“Their latest bogey is that the temporary TRIPS waiver for suspending [intellectual property rights] in combating the COVID-19 pandemic ‘would risk handing novel technology to China and Russia’ . . . ” (quoting Kuchler & Williams, *supra*)).

17. For discussions of the U.S.-China trade war, see generally LAWRENCE J. LAU, *THE CHINA–U.S. TRADE WAR AND FUTURE ECONOMIC RELATIONS* (2019); Peter K. Yu, *US-China Intellectual Property Trade Wars*, in *RESEARCH HANDBOOK ON TRADE WARS* 271 (Zeng Ka & Liang Wei eds., 2022) [hereinafter Yu, *Trade Wars*]; ANGELA HUYUE ZHANG, *CHINESE ANTITRUST EXCEPTIONALISM: HOW THE RISE OF CHINA CHALLENGES GLOBAL REGULATION* 203–34 (2021); Henry Gao, *WTO Reform and China: Defining or Defiling the Multilateral Trading System?*, 62 *HARV. INT’L L.J. (SPECIAL ISSUE)* 1, 26–33 (2021); Lee Jyh-an, *Shifting IP Battlegrounds in the U.S.-China Trade War*, 43 *COLUM. J.L. & ARTS* 147 (2020).

18. *China COVID-19 Vaccine Tracker*, BRIDGE CONSULTING (BEIJING) CO., <https://bridgebeijing.com/our-publications/our-publications-1/china-covid-19-vaccines-tracker/> [<https://perma.cc/E7Z3-LQSZ>] (last visited July 16, 2022); Song Wanyuan, *Covid-19 Vaccines: Has China Made More Than Other Countries Combined?*, *BBC NEWS* (Oct. 10, 2021), <https://www.bbc.com/news/58808889> [<https://perma.cc/GDH6-2UW8>].

19. See *supra* text accompanying note 12.

20. See Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 *MICH. L. REV. ONLINE* 170, 174 (2020) (“Some types of vaccines—such as live virus vaccines—are particularly sensitive to temperature changes, a feature that poses enhanced problems in reaching vaccine markets in remote areas of the Global South.”); Adam Kamradt-Scott, *Creating a COVID-19 Vaccine Is Only the First Step. It’ll Take Years to Manufacture and Distribute*, *THE CONVERSATION* (Aug. 17, 2020), <https://theconversation.com/creating-a-covid-19-vaccine-is-only-the-first-step-itll-take-years-to-manufacture-and-distribute-144352> [<https://perma.cc/292M-B46Z>] (“Most vaccines need to be transported in cold storage, which presents a problem for many parts of the world where electricity failure is a common feature of daily life.”). In fact, “[c]onfidential EU documents obtained by a German media outlet . . . revealed that over half of EU

and Sinovac vaccines for emergency use, respectively.<sup>21</sup> In July, the COVID-19 Vaccines Global Access Initiative (COVAX) entered into an agreement to purchase 550 million doses of vaccines from China, earning the ire of U.S. politicians, commentators, and the mass media.<sup>22</sup> According to the WTO–IMF COVID-19 Vaccine Trade Tracker, which built on the work of the International Monetary Fund (IMF) and the WTO,<sup>23</sup> China accounted for about a third of the world’s exports of COVID-19 vaccine doses.<sup>24</sup>

From the standpoints of both global competition and global health, it is interesting to observe China’s active worldwide distribution of home-grown vaccines and its strategies behind such distribution. As a recent study on China’s pandemic diplomacy declares, “While the United States and many other wealthy countries have donated large quantities of vaccines to

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member states wanted more ‘traditional’ vaccines and were ‘very little interested’ in the new mRNA vaccines developed by Pfizer BioNTech and Moderna, mainly because they required subzero temperatures for storage and were more expensive.” COLIN KAHL & THOMAS WRIGHT, *AFTERSHOCKS: PANDEMIC POLITICS AND THE END OF THE OLD INTERNATIONAL ORDER* 300 (2021).

21. See *WHO Lists Additional COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WORLD HEALTH ORG. (May 7, 2021), <https://www.who.int/news/item/07-05-2021-who-lists-additional-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations> [https://perma.cc/FDR2-BCNC] (validating Sinopharm vaccines for emergency use); *WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WORLD HEALTH ORG. (June 1, 2021), <https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations> [https://perma.cc/JB6Z-KP5L] (validating Sinovac vaccines for emergency use).

22. Julia Hollingsworth, *COVAX Signs Deal for 550 Million Chinese Covid-19 Vaccines amid Questions over Efficacy*, CNN (July 13, 2021), <https://www.cnn.com/2021/07/13/asia/covax-china-vaccines-intl-hnk/index.html> [https://perma.cc/YP5L-ZXVM]; see also Josh Rogin, *China’s Vaccine Profiteering at the U.N. Is Being Funded by U.S. Taxpayers*, WASH. POST (July 15, 2021, 7:30 PM), <https://www.washingtonpost.com/opinions/2021/07/15/china-charging-un-for-vaccine-when-us-is-donating/> [https://perma.cc/FPQ8-J8NT].

23. *IMF–WHO COVID-19 Vaccine Tracker*, INT’L MONETARY FUND, <https://www.imf.org/en/Topics/imf-and-covid19/IMF-WHO-COVID-19-Vaccine-Tracker> (Sept. 8, 2022).

24. *WTO-IMF COVID-19 Vaccine Trade Tracker*, WORLD TRADE ORG. (Apr. 28, 2022), [https://www.wto.org/english/tratop\\_e/covid19\\_e/vaccine\\_trade\\_tracker\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm) [https://perma.cc/7MYM-ZG73]. The latest data are from May 31, 2022. The tracker no longer provides updates. *Id.*

COVAX . . . , China predominantly engages countries bilaterally to augment its bilateral influence. Only a small proportion of Chinese vaccine exports have been allocated to COVAX or other multilateral mechanisms.”<sup>25</sup> This report further laments how a significantly large portion of Chinese vaccines was sold rather than donated.<sup>26</sup> While the report’s authors are right to point out the difference between sales and donations, what problem the former would pose from a global health standpoint will depend on whether the sale price greatly exceeds the production cost.<sup>27</sup> Sales at cost or with a deep bulk dis-

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25. China Power Team, *Is China’s Covid-19 Diplomacy Succeeding?*, CTR. FOR STRATEGIC & INT’L STUD. (Mar. 17, 2022), <https://chinapower.csis.org/china-covid-medical-vaccine-diplomacy/> [<https://perma.cc/EW2A-QX2B>]. For discussions of China’s global pandemic diplomacy, see generally MARIA EUGENIA BRIZUELA DE ÁVILA ET AL., *US-CHINA VACCINE DIPLOMACY: LESSONS FROM LATIN AMERICA AND THE CARIBBEAN* (Wazim Mowla ed., 2022); MARGARET MYERS, *CHINA’S COVID-19 DIPLOMACY IN LATIN AMERICA AND THE CARIBBEAN: MOTIVATIONS AND METHODS* (2021); Yu, *China, the TRIPS Waiver*, *supra* note 8; Denny Roy, *China’s Pandemic Diplomacy* (E.-W. Ctr., Asia Pacific Issues No. 144, 2020); China Power Team, *supra*; William Wang & Holly Snape, *Why a Coronavirus Vaccine Is Politically Valuable to China*, *THE CONVERSATION* (Oct. 20, 2020), <https://theconversation.com/why-a-coronavirus-vaccine-is-politically-valuable-to-china-148136> [<https://perma.cc/3534-KKQZ>]. For discussions of pandemic diplomacy in general, see generally PETER J. HOTEZ, *PREVENTING THE NEXT PANDEMIC: VACCINE DIPLOMACY IN A TIME OF ANTI-SCIENCE* (2021); KAHL & WRIGHT, *supra* note 20.

26. See China Power Team, *supra* note 25 (“The overwhelming majority of China’s public health diplomacy has come in the form of commercial sales rather than donations.”).

27. Cf. Sarah Joseph & Gregory Dore, *Vaccine Apartheid: A Human Rights Analysis of COVID-19 Vaccine Inequity*, 31 J. TRANSNAT’L L. & POL’Y 145, 168 (2021–2022) (criticizing Pfizer for “taking full commercial advantage of its monopoly control of its vaccines”). The Author has yet to come across information about the costs of and prices for Chinese vaccines, although the prices for vaccines from AstraZeneca, Pfizer, and Moderna have been unofficially disclosed. See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting: Held in the Centre William Rappard on 10–11 March 2021*, ¶ 284, WTO Doc. IP/C/M/98/Add.1 (July 30, 2021) (“It is well reported that South Africa has paid USD 5.25 a dose for a version of the vaccine manufactured in India while it seems that the European Commission paying only USD 3.50 per shot. Uganda seems to have paid USD 8.50 a dose.”); Behrang Kianzad & Jakob Wested, ‘No-One Is Safe Until Everyone Is Safe’—Patent Waiver, Compulsory Licensing and COVID-19, 5 EUR. PHARM. L. REV. 71, 73 (2021) (“The prices paid by the European Union detailed by [a] now-deleted tweet ranged from 1.78 for AstraZeneca shot to 12.00 for Pfizer / BioNTech and \$18.00 for Moderna shots, respectively.”).

count can still provide an important contribution to combating the pandemic.

Although most observations on Chinese vaccines have focused on the country's global pandemic diplomacy, the development of these vaccines provides useful insight into the country's changing landscape of pharmaceutical innovation. Only four decades ago, commentators lamented China's poverty and technological backwardness. As the now-defunct U.S. Office of Technology Assessment stated in its 1987 study, "China is still a very poor country, and technology transfer [from the United States and other developed countries] can be an important element in humanitarian efforts to help a billion people move out of poverty."<sup>28</sup> In the 1980s and 1990s, if anything technology-related in China captured the attention of Western media and commentators, those stories usually concerned piracy and counterfeiting.<sup>29</sup> This line of observation was still quite common even as late as the 2008 Beijing Olympics.<sup>30</sup>

Today, however, the landscape of pharmaceutical innovation in China has dramatically changed. That landscape began to shift in the mid-2000s.<sup>31</sup> In June 2008, the State Council adopted a National Intellectual Property Strategy, which "provided a comprehensive plan to improve the creation, utilization, protection, and administration of intellectual property

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28. CONG. OFF. OF TECH. ASSESSMENT, OTA-ISC-340, TECHNOLOGY TRANSFER TO CHINA 3 (1987).

29. 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); Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in Post-WTO China*, 55 AM. U. L. REV. 901 (2006).

30. For discussions of piracy and counterfeiting issues in relation to the Beijing Olympics, see generally Peter K. Yu, *The Curious Case of Fake Beijing Olympics Merchandise*, in TRADEMARK PROTECTION AND TERRITORIALITY CHALLENGES IN A GLOBAL ECONOMY 259 (Irene Calboli & Edward Lee eds., 2014); Doris Estelle Long, *Trademarks and the Beijing Olympics: Gold Medal Challenges*, 7 J. MARSHALL REV. INTELL. PROP. L. 433 (2008).

31. See Yu, *China's Innovative Turn*, *supra* note 8, at 599–602 (discussing China's innovative turn).

rights.”<sup>32</sup> Paragraph 7 specifically emphasized the need for the active development of independent or self-controlled intellectual property (*zizhu zhishi chanquan*).<sup>33</sup> A few months later, China undertook a complete overhaul of its Patent Law—the first revamp of a major intellectual property law following the country’s WTO accession in December 2001.<sup>34</sup> Known officially as the Third Amendment to the Patent Law, this overhaul allowed China to make substantial adjustments to its patent system based on internal needs, as opposed to external considerations.<sup>35</sup>

Although China has yet to 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,<sup>36</sup> the country is no longer content to serve only as the world’s leading supplier of active pharmaceutical ingredients (API).<sup>37</sup> Instead, China wants to become a major player in the development of

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32. Peter K. Yu, *A Half-Century of Scholarship on the Chinese Intellectual Property System*, 67 AM. U. L. REV. 1045, 1079 (2018); see also *id.* at 1079–85 (2018) (discussing the National Intellectual Property Strategy).

33. *Id.* at 1080.

34. *Accessions: China*, WORLD TRADE ORG., [https://www.wto.org/english/thewto\\_e/acc\\_e/a1\\_chine\\_e.htm](https://www.wto.org/english/thewto_e/acc_e/a1_chine_e.htm) [<https://perma.cc/EVJ7-WN4B>] (last visited Apr. 3, 2023).

35. See Guo He, *Patents*, in CHINESE INTELLECTUAL PROPERTY AND TECHNOLOGY LAWS 25, 28 (Rohan Kariyawasam ed., 2011) (“The impetus for the early amendments [in 1992 and 2000] 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.”); Peter K. Yu, *The Transplant and Transformation of Intellectual Property Laws in China*, in GOVERNANCE OF INTELLECTUAL PROPERTY RIGHTS IN CHINA AND EUROPE 20, 27–28 (Nari Lee et al. eds., 2016) (noting that “China, for the first time, adjusted its patent standards based on its own needs”).

36. Yu, *China’s Innovative Turn*, *supra* note 8, at 594.

37. See WORLD HEALTH ORG., CHINA POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 17–18 (2017) (prepared by Frederick Abbott) (discussing China’s production and export of APIs); Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 363 (2008) (“[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.”).

research-based pharmaceutical and biological products.<sup>38</sup> As this Author observed in an earlier book chapter:

Today, [China] has the world's second largest pharmaceutical market, behind only the US. With a market "worth more than \$120 billion," China "account[s] for 20% of total global API output" and "produces over 2000 API drug products, with annual production capacity exceeding 2 million tons." In addition, the country produces about 4 percent of the world's new pharmaceutical products.<sup>39</sup>

To support these aspirations, China has recently introduced some important legal and regulatory reforms in both the patent area and in relation to pharmaceuticals. In October 2020, amid the COVID-19 pandemic, China adopted the Fourth Amendment to the Patent Law, which entered into effect on June 1, 2021.<sup>40</sup> Paralleling the Hatch-Waxman Act of 1984 in the United States,<sup>41</sup> Article 42 of the amended statute grants a limited extension of the patent term for up to five

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38. See 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 3 (2019) ("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 toward producing innovative drugs."); WORLD HEALTH ORG., *supra* note 37, 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)); Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46 FLA. ST. U. L. REV. 641, 694 (2019) ("China wants to develop a research-based pharmaceutical industry.").

39. Peter K. Yu, *From Struggle to Surge: China's TRIPS Experience and Its Lessons for Access to Medicines*, in INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES: TRIPS AGREEMENT, HEALTH, AND PHARMACEUTICALS 172, 179 (Srividhya Ragavan & Amaka Vanni eds., 2021).

40. Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Oct. 17, 2020, effective June 1, 2021) [hereinafter 2020 Patent Law].

41. Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (providing a limited extension of the patent term based on the period during which a pharmaceutical product undergoes regulatory review).

years to compensate for the time lost when a pharmaceutical product undergoes regulatory review.<sup>42</sup> Article 76 of the Patent Law, along with the Provisional Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes, further introduced a new patent linkage system that would prevent the marketing approval of the generic version of a patented drug until after the expiration of its patent.<sup>43</sup> These two reforms align well with the provisions found in TRIPS-plus bilateral, regional, and plurilateral agreements negotiated by the United States.<sup>44</sup>

In April 2018, the National Medical Products Administration of China released the draft Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products.<sup>45</sup> Article 5 provides six years of market exclusivity to undisclosed test or other data for innovative drugs (*chuangxin yao*) and twelve years of similar protection for innovative thera-

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42. 2020 Patent Law, *supra* note 40, art. 42; *see also* Yu, *China's Innovative Turn*, *supra* note 8, at 604 (discussing Article 43 of the draft amendment, which has become Article 42 of the amended statute).

43. 2020 Patent Law, *supra* note 40, art. 76; Provisional Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (promulgated by the Nat'l Med. Prods. Admin. & China Nat'l Intell. Prop. Admin., July 4, 2021, effective July 4, 2021), <https://www.nmpa.gov.cn/directory/web/nmpa/images/1625323300528019998.doc> [<https://perma.cc/TJM9-N8PE>] (China). *See generally* Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303 (2008); Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RESV. J. INT'L L. 79, 88–91 (2004).

44. *See, e.g.*, Dominican Republic-Central America Free Trade Agreement, arts. 15.9.6, 15.10.2, Aug. 5, 2004, <https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text> [<https://perma.cc/TML5-7YD3>] (providing for Hatch-Waxman extension and patent linkage); United States-Australia Free Trade Agreement, Austl.-U.S., arts. 17.9.8, 17.10.4, May 18, 2004, <https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta> [<https://perma.cc/LXZ8-9JCP>] (providing for Hatch-Waxman extension and patent linkage); United States-Singapore Free Trade Agreement, Sing.-U.S., arts. 16.7.8, 16.8.4, May 6, 2003, <https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text> [<https://perma.cc/FZY5-Q2F4>] (providing for Hatch-Waxman extension and patent linkage).

45. Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products (Draft, Apr. 2018), <https://chinaipr2.files.wordpress.com/2018/04/draftdataexclusivityrules.doc> [<https://perma.cc/4NET-GFQA>] (China).

peutic biological products (*chuangxin zhiliao yong shengwu zhipin*).<sup>46</sup> While the WTO accession protocol already required China to offer the former,<sup>47</sup> the latter would put China in parity with the United States, which offers twelve years of protection to undisclosed test or other data for biological products.<sup>48</sup> The proposed standard would also raise the protections for biological products in China to a level higher than the levels found in regional and plurilateral trade agreements.<sup>49</sup> This

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46. *Id.* art. 5. *But see* Mark Cohen, *Unpacking the Role of IP Legislation in the Trade War*, CHINA IPR (May 19, 2019), <https://chinaipr.com/2019/05/19/unpacking-the-role-of-ip-legislation-in-the-trade-war> [<https://perma.cc/Y6F8-NYQY>] (“There were . . . rumors that China and [the United States Trade Representative] has scaled back regulatory data protection for biologics from the 12 years that had originally been proposed by China in 2018 to the 10 year period provided by the US Mexico Canada Free Trade Agreement.”).

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

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.

Working Party on China’s Status as a Contracting Party, World Trade Organization, *Report of the Working Party on the Accession of China*, ¶ 284, WTO Doc. WT/ACC/CHN/49 (Oct. 1, 2001); *see also* Yu, *China’s Innovative Turn*, *supra* note 8, at 603 (discussing China’s WTO commitments in this area).

48. 42 U.S.C. § 262(k)(7)(A).

49. *See* Yu, *China’s Innovative Turn*, *supra* note 8, at 605–07 (comparing the proposed standard with standards found in regional and plurilateral trade agreements).

rather high standard of protection is surprising, considering that China has yet to become a world leader in the development of biological products and personalized medicines.<sup>50</sup> To a large extent, the proposed standard reflects more about the country's aspirations than its current needs.

In the past decade, China has made important strides in the use and development of artificial intelligence (AI) and machine learning in the medical and health arenas. As Tencent CEO Ma Huateng observed in the *Global Innovation Index 2019* report:

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.<sup>51</sup>

From 1985 to 2017, "China ranked fourth in the total number of healthcare AI patent applications filed, contributing to 12% of the total."<sup>52</sup> In 2016, China had already "surpassed Japan and the European Union to become the world's second largest healthcare AI applicant . . . , which reflect[ed] the strong momentum of medical technology innovation in China."<sup>53</sup> During the COVID-19 pandemic, the country has widely deployed

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50. See WORLD HEALTH ORG., *supra* note 37, at 19–21 (discussing the growing development of biological products in China).

51. Ma Huateng, *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, 103 (Soumitra Dutta et al. eds., 2019).

52. *Id.* at 104.

53. *Id.*

AI to facilitate pandemic prevention and control, and to support vaccine development.<sup>54</sup>

Taken together, these legislative and regulatory reforms and the advances in health-related AI reveal China's ambition to develop national champions in the pharmaceutical and biological sectors and in the health arena. In May 2015, the State Council released the *Made in China 2025* strategic plan, which identified biomedicine and high-performance medical devices as one of ten priority sectors.<sup>55</sup> Among the medical products and technologies that China intended to develop were “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.”<sup>56</sup> In September 2021, the State Council further released *An Outline for Building a Powerful Intellectual Property Nation (2021–2035)*, which set ambitious targets for making China a strong intellectual property power.<sup>57</sup> Gone were the days when China prima-

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54. See, e.g., Wang Ting et al., *Artificial Intelligence Against the First Wave of COVID-19: Evidence from China*, 22 BMC HEALTH SERVS. RSCH. 767 (2022) (discussing the use of artificial intelligence in COVID-19 prevention and control in China from December 2019 to April 2020); Emily Weinstein, *China's Use of AI in Its COVID-19 Response* (Ctr. for Sec. & Emerging Tech., Data Brief, 2020), <https://cset.georgetown.edu/publication/chinas-use-of-ai-in-its-covid-19-response/> [<https://perma.cc/E9GX-KWHW>] (summarizing the findings of a report released by a Chinese government think tank on the use of AI in China to combat COVID-19); Victor Liang, *Baidu's AI-Related Patented Technologies: Doing Battle with COVID-19*, WIPO MAG. (June 2020), [https://www.wipo.int/wipo\\_magazine/en/2020/02/article\\_0003.html](https://www.wipo.int/wipo_magazine/en/2020/02/article_0003.html) [<https://perma.cc/4LDJ-AHXZ>] (“The LinearDesign algorithm, developed by Baidu Research in collaboration with Oregon State University and University of Rochester in the USA, is being used by mRNA vaccine companies to accelerate and optimize the design of possible COVID-19 vaccines.”).

55. U.S. CHAMBER OF COM., *MADE IN CHINA 2025: GLOBAL AMBITIONS BUILT ON LOCAL PROTECTIONS* 10 (2017).

56. GRYPHON SCIENTIFIC, LLC & RHODIUM GROUP, LLC, *supra* note 38, at 38.

57. STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, *AN OUTLINE FOR BUILDING A POWERFUL INTELLECTUAL PROPERTY NATION (2021–2035)* (2021), [http://www.gov.cn/zhengce/2021-09/22/content\\_5638714.htm](http://www.gov.cn/zhengce/2021-09/22/content_5638714.htm) [<https://perma.cc/2BDR-H95B>] (in Chinese).

rily utilized imitation to foster economic and technological catch-up.<sup>58</sup>

In sum, China's participation in the global pandemic response has shown the country's improved ability to compete with the United States, the European Union, India, and other leaders in the health arena. As policymakers explore what international regulatory standards to develop during the inter-pandemic period and in the post-COVID-19 era, they should keep in mind the country's changing competitive position. They should also pay attention to the shifting pharmaceutical landscape in China and the country's growing role and responsibilities in global health governance.<sup>59</sup> All of these changes will not only enable China to provide contributions that were not available two decades ago, but will also create complications that we have not seen before.

### III. INTERNATIONAL REGULATORY CHALLENGES

In view of the different roles China can now play in the global health arena, it will be important for other countries and their policymakers to explore how best to engage with China when developing new international regulatory standards during the inter-pandemic period and in the post-COVID-19 era. For analytical purposes, this Article focuses on standards at the intersection of intellectual property, international trade, and public health. Specifically, it identifies chal-

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58. See Xue Lan & Liang Zheng, *Relationships Between IPR and Technology Catch-up: Some Evidence from China*, in *INTELLECTUAL PROPERTY RIGHTS, DEVELOPMENT, AND CATCH-UP: AN INTERNATIONAL COMPARATIVE STUDY* 317 (Hiroyuki Odagiri et al. eds., 2010) (discussing China's catch-up process following its reopening to the outside world in the late 1970s and documenting the adaptation of domestic firms, such as Huawei Technologies, to the intellectual property system through gradual innovation); Lee, *supra* note 17, at 151 ("China's approach to acquiring new technologies from the western world has shifted from low-end imitation to obtaining advanced technologies through corporate control."); Peter K. Yu, *Piracy, Prejudice, and Perspectives: An Attempt to Use Shakespeare to Reconfigure the U.S.-China Intellectual Property Debate*, 19 B.U. INT'L. L.J. 1, 22-28 (2001) (discussing China's past efforts to play catch-up with developed countries and its self-strengthening worldview).

59. See generally Jeremy Youde, *China's Role in Global Health Governance*, in *ROUTLEDGE HANDBOOK ON THE POLITICS OF GLOBAL HEALTH* 172 (Richard Parker & Jonathan García eds., 2019) (discussing China's role in global health governance).

allenges and complications in three areas: (1) vaccine development and production; (2) eligibility restrictions to special negotiated arrangements to combat COVID-19; and (3) active public-sector participation in the development of health products and technologies. While the discussion of each area is important in the pandemic context, a greater appreciation of the challenges and complications in these three areas will illuminate other areas. Because the outcome of the analysis in each area will vary significantly depending on the focus, this Part discusses the perspectives of global competition and global health alongside each other.

#### A. *Vaccine Development and Production*

##### 1. *Global Competition*

The previous Part discussed China's eagerness to play catch-up with other technology leaders in the health arena. By the time the next pandemic occurs, China will be in a good position from the beginning of the outbreak to develop vaccines that use novel rather than conventional technology. From a global competition standpoint, it is not difficult to see why policymakers in other countries hesitate to support the adoption of new or modified international regulatory standards that would accelerate the development of China's pharmaceutical sector.

To be sure, the U.S. pharmaceutical industry's use of the potential transfer of mRNA technology to China to justify their opposition to the COVID-19 TRIPS waiver was self-serving.<sup>60</sup> Given the waiver's intended goal of reducing intellectual property protection,<sup>61</sup> these companies would have opposed the

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60. See *supra* text accompanying note 16.

61. See Bryan Mercurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 VA. J. INT'L L. ONLINE 9, 16–18 (2021) [hereinafter Mercurio, *WTO Waiver*] (discussing how the proposed waiver would undermine research and development and innovation); Peter K. Yu, *Deferring Intellectual Property Rights in Pandemic Times*, 74 HASTINGS L.J. 489, 507 (2023) [hereinafter Yu, *Deferring Intellectual Property Rights*] (discussing the potential for the proposed waiver to undermine the incentive frameworks for developing medical products and technologies needed to combat COVID-19); Reto M. Hilty et al., *Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021*, at 5 (Max Planck Inst. for Innovation & Competition, Research Paper No. 21-13, 2021), <https://www.ip.mpg.de/>

proposed instrument regardless. Nevertheless, it is not difficult to appreciate their concerns over efforts that would accelerate the development of novel vaccine technology in China.

For many countries and their policymakers, the preferred method of engagement with China is to slow down the development of its pharmaceutical sector, especially when such development may involve unfair competition. As the Office of the U.S. Trade Representative noted in its lengthy reports on its Section 301 investigation into Chinese laws, policies, and practices in the areas of intellectual property, innovation, and technology development, China has deployed systematic, state-directed actions in the past few decades to climb up the technological ladder and to play catch-up with the United States and other developed countries.<sup>62</sup> To a large extent, the ongoing U.S.-China trade war<sup>63</sup> and the adoption of the CHIPS and

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fileadmin/ipmpg/content/stellungnahmen/2021\_05\_25\_Position\_statement\_Covid\_IP\_waiver.pdf [https://perma.cc/P2YW-MVBQ] (“A waiver of [intellectual property] protection would not serve the interest of . . . society, as it would create a disincentive for companies to pursue research in those areas.”).

62. See OFF. 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) (providing the final report of the Section 301 investigation conducted during the Trump Administration); OFF. 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). For the Author’s response to these reports on the issue of forced technology transfer, see generally Peter K. Yu, *The U.S.–China Forced Technology Transfer Dispute*, 52 SETON HALL L. REV. 1003 (2022) [hereinafter Yu, *Forced Technology Transfer*].

63. See China Briefing Team, *U.S.–China Relations in the Biden-Era: A Timeline*, CHINA BRIEFING (Oct. 12, 2021), <https://www.china-briefing.com/news/us-china-relations-in-the-biden-era-a-timeline/> [https://perma.cc/3AX7-T2UQ] (providing an updated timeline of U.S.-China developments during the Biden Administration); Dorcas Wong & Alexander Chipman Koty, *The US–China Trade War: A Timeline*, CHINA BRIEFING (Aug. 25, 2020), <https://www.china-briefing.com/news/the-us-china-trade-war-a-timeline/> [https://perma.cc/BP5Z-F7LD] (providing a timeline of the trade tariffs that the United States and China have imposed on each other during the Trump Administration); see also *supra* note 17 (collecting sources that discuss the U.S.-China trade war).

Science Act of 2022<sup>64</sup> reflects the United States' efforts to develop policy responses to these actions.

In the near future, the development of new international regulatory standards that would implicate U.S.-China policies will remain contentious. As Chinese firms continue to make technological advances in areas such as 5G telecommunications, big data analytics, artificial intelligence, robotics, quantum computing, and biomedicine, the competition between the two countries can only intensify.<sup>65</sup> The concerns among U.S. policymakers and industries about China's increasing global competitiveness are therefore not going to disappear any time soon.

## 2. *Global Health*

From a global health standpoint, however, the outcome of the analysis will be very different, if not diametrically opposed. Unlike the narrative in the previous section, the international community will have strong incentives to support China in developing better vaccines, including those utilizing novel technology.

To begin with, China has been the breeding ground for many viruses that have eventually caused pandemics or epidemics, such as SARS, H5N1, and SARS-CoV-2.<sup>66</sup> As we

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64. An Act Making Appropriations for Legislative Branch for the Fiscal Year Ending September 30, 2022, and for Other Purposes, Pub. L. No. 117-167 (2022). See generally CHRIS MILLER, *CHIP WAR: THE FIGHT FOR THE WORLD'S MOST CRITICAL TECHNOLOGY* 243-343 (2022) (discussing the U.S.-China conflict over microchip technology).

65. See LAU, *supra* note 17, at 5 ("The competition between China and the U.S. in terms of being the largest economy in the world, as well as competition in the core technologies of the 21st century, such as artificial intelligence and quantum computing, probably cannot be avoided. It is likely to become the 'new normal'."); Yu, *Trade Wars*, *supra* note 17, at 280 (noting that "bilateral competition in frontier technologies—such as 5G, big data analytics, artificial intelligence, robotics, quantum computing and biomedicine—are unlikely to slow down in the near future").

66. See DAVID P. FIDLER, *SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE* 72 (2004) ("Public health experts have kept an eye on southern China and southeast Asia as a possible, if not the probable, source of the long-anticipated, killer pandemic influenza virus."); 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."); Peter K. Yu, *Virotech Patents, Viropiracy, and Viral*

have painfully learned from past public health crises with these viruses, the easiest way to combat a virus is to target the place of outbreak.<sup>67</sup> By the time the virus has spread globally, it is just too late. Consider, for example, the impacts of both the SARS and COVID-19 outbreaks. Although SARS took the lives of only fewer than 800 individuals, the economic toll of the epidemic reached over \$40 billion.<sup>68</sup> Compared with SARS, COVID-19 has taken a much heavier human toll of more than six million lives<sup>69</sup> while exacting tens of trillions of dollars in economic damage.<sup>70</sup> To avoid such devastation, the

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*Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1652 (2013) [hereinafter Yu, *Virotech Patents*] (“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.”).

67. See SARA E. DAVIES, *GLOBAL POLITICS OF HEALTH* 140 (2012) (“The first line of defence is ‘prevention, treatment and control programs’ before the disease reached US shores.” (quoting a USAID document)); Kathryn White & Maria Banda, *The Role of Civil Society in Pandemic Preparedness*, in *INNOVATION IN GLOBAL HEALTH GOVERNANCE* 105, 118 (Andrew F. Cooper & John J. Kirton eds., 2009) (“Instead of hoarding the vaccine, the West ought to release it to the most vulnerable, because the regions the first to be hit would also be the first line of defence.”); see also John D. Kraemer & Mark J. Siedner, *The Effect of Ebola Virus Disease on Health Outcomes and Systems in Guinea, Liberia, and Sierra Leone*, in *GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA* 55, 67 (Sam F. Halabi et al. eds., 2017) (noting that resources “would likely be more cost-effectively deployed” to prevent epidemics than to control them).

68. See Georges C. Benjamin, *Afterword* to TIM BROOKES, *BEHIND THE MASK: HOW THE WORLD SURVIVED SARS, THE FIRST EPIDEMIC OF THE 21ST CENTURY* 235–36 (2004) (“Over 8,000 people from 29 countries became ill and about 774 died. . . . [SARS] did . . . cost over US\$ 40 billion and served as a global wake-up call.”).

69. WHO *Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG., <https://covid19.who.int> [<https://perma.cc/Y2JL-6LQZ>] (last visited Mar. 16, 2022).

70. See David M. Cutler & Lawrence H. Summers, *The COVID-19 Pandemic and the \$16 Trillion Virus*, 324 JAMA 1495, 1496 (2020) (estimating that the total cumulative financial costs of the COVID-19 pandemic relating to the lost output and health reduction at more than \$16 trillion); Australian Nat’l Univ., *Economic Pain: COVID-19 Pandemic Will Cost Global Economy \$21 Trillion*, SCI. TECH. DAILY (July 5, 2020), <https://scitechdaily.com/economic-pain-covid-19-pandemic-will-cost-global-economy-21-trillion/> [<https://perma.cc/ZL3N-WPSS>] (providing a July 2020 estimate that the pandemic’s global economic toll could reach as high as \$21 trillion); Shahar Ziv, *Coronavirus Pandemic Will Cost U.S. Economy \$8 Trillion*, FORBES (June 2, 2020), <https://www.forbes.com/sites/shaharziv/2020/06/02/coronavirus-pandemic-will-cost-us-economy-8-trillion/#5ce83d7c15e4> [<https://perma.cc/U2LC-L5J3>]

international community has strong incentives to ensure that countries vulnerable to viral outbreaks, including China, will have the latest vaccine technology the next time these outbreaks occur.<sup>71</sup>

While the size of the Chinese economy virtually guarantees that the country will have the resources needed to develop new technology in anticipation of future viral outbreaks and pandemics,<sup>72</sup> any effort to curtail China's technological development in the health arena seems counterproductive. Indeed, countries should avoid setting international regulatory standards that focus primarily on preserving their competitive and comparative advantage. They should instead embrace standards that would strengthen local technological capacity—whether in China or in other parts of the world.<sup>73</sup> As noted in

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(estimating that “the pandemic would cost \$7.9 trillion in real economic output, or a staggering \$16 trillion over the next 10 years without adjusting for inflation”).

71. See SIMON RUSHTON, *SECURITY AND PUBLIC HEALTH: PANDEMICS AND POLITICS IN THE CONTEMPORARY WORLD* 37–38 (2019) (“The weakness of health systems in Guinea, Liberia and Sierra Leone led to what should have been at worst a localized epidemic becoming a regional problem, with . . . the potential to transform into a global pandemic.”); SCOWCROFT INST. OF INT’L AFFS., TEXAS A&M UNIV., *THE GROWING THREAT OF PANDEMICS: ENHANCING DOMESTIC AND INTERNATIONAL BIOSECURITY* 31 (2017) (“If localized outbreaks become regional epidemics and/or global pandemics because laboratories, clinics, and hospitals in developing nations do not have the ability to rapidly detect and control outbreaks, then the devastation caused by high-impact infectious diseases will enter the United States, where we would face our own surge capacity struggles.”); Peter K. Yu, *Modalities, Challenges, and Possibilities: An Introduction to the Pharmaceutical Innovation Symposium*, 7 TEX. A&M J. PROP. L. 1, 29 (2021) (“Because many countries that are breeding grounds for viral outbreaks also struggle with poverty and infrastructure problems, they need as much international assistance as they can secure.”).

72. See *infra* text accompanying note 90 (noting that China has the world’s second largest or largest economy).

73. See Peter K. Yu, *The COVID-19 TRIPS Waiver and the WTO Ministerial Decision*, in *IPR IN TIMES OF CRISIS: LESSONS LEARNED FROM THE COVID-19 PANDEMIC* (Jens Schovsbo ed., forthcoming 2023) [hereinafter Yu, *Ministerial Decision*] (noting the need to improve the developing countries’ local research and production capacities to enable them to better prepare for future pandemics or other global and regional crises). See generally Germán Velásquez, *Re-thinking Global and Local Manufacturing of Medical Products After COVID-19* (S. Ctr., Research Paper No. 118, 2020), [https://www.southcentre.int/wp-content/uploads/2020/09/RP\\_118\\_reduced-1.pdf](https://www.southcentre.int/wp-content/uploads/2020/09/RP_118_reduced-1.pdf) [<https://perma.cc/4JHT-FG4Z>] (underscoring the need to start or expand the local production of pharmaceuticals in developing countries).

the widely used slogan during the COVID-19 pandemic, “[n]o one is safe until everyone is safe.”<sup>74</sup>

One difficult question concerns the connection between global competition and global health<sup>75</sup>—that is, whether China’s growing technological development in the health arena will eventually cause the country to become more reluctant to share viral samples with other countries or intergovernmental bodies,<sup>76</sup> or to transfer valuable pharmaceutical and health technology to other developing countries.<sup>77</sup> After all, the developed countries’ continuous refusal to transfer technology to their less developed counterparts remains a key problem in the international intellectual property regime.<sup>78</sup> There are two quick responses, however. First, it should not be forgotten that “[p]rompt collaboration by China for sequencing and releasing the full genome of the SARS-Cov-2 virus by mid-January [2020] enabled research labs around the world to develop test kits to begin detecting infections of COVID-19.”<sup>79</sup>

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74. *What Is the ACT-Accelerator*, WORLD HEALTH ORG., <https://www.who.int/initiatives/act-accelerator/about> [https://perma.cc/6BAY-6DY8] (last visited Mar. 18, 2023).

75. Thanks to Rochelle Dreyfuss and Madhavi Sunder for pushing the Author to consider this line of questioning.

76. These concerns recall the viral sovereignty positions taken by Indonesia and other countries in late 2000s. For discussions of these positions, see generally VIRAL SOVEREIGNTY AND TECHNOLOGY TRANSFER: THE CHANGING GLOBAL SYSTEM FOR SHARING PATHOGENS FOR PUBLIC HEALTH RESEARCH (Sam Halabi & Rebecca Katz eds., 2020); Sam F. Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS HEALTH L. 101 (2019); Yu, *Virotech Patents*, *supra* note 66, at 1604–18.

77. See Yu, *China, the TRIPS Waiver*, *supra* note 8 (discussing whether China’s growing ambition to become an intellectual property power will reduce its willingness to transfer technology to other developing countries).

78. For discussions of the developed countries’ reluctance to transfer technology to developing countries, see generally INTERNATIONAL TECHNOLOGY TRANSFER: THE ORIGINS AND AFTERMATH OF THE UNITED NATIONS NEGOTIATIONS ON A DRAFT CODE OF CONDUCT (Surendra J. Patel et al. eds., 2001); SUSTAINABLE TECHNOLOGY TRANSFER: A GUIDE TO GLOBAL AID AND TRADE DEVELOPMENT (Hans Henrik Lidgard et al. eds., 2012); Yu, *Forced Technology Transfer*, *supra* note 62, at 1025–39.

79. Viviana Muñoz Tellez, *The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines* (S. Ctr., Policy Brief No. 73, 2020); see Jon Cohen, *Chinese Researchers Reveal Draft Genome of Virus Implicated in Wuhan Pneumonia Outbreak*, SCI. (Jan. 11, 2020), <https://www.sciencemag.org/news/2020/01/chinese-researchers-reveal>

As China becomes more globally competitive in the pharmaceutical sector, it may be even more confident in its local industry than today, and may therefore see less urgency in retaining viral samples or genomic information. Second, China continues to value support for other developing countries, due in part to its eagerness to retain leadership in the developing world and in part to its strategic effort to gain soft power.<sup>80</sup> Thus, China is likely to continue to provide support to other developing countries<sup>81</sup> even though it remains focused on building national champions in the pharmaceutical and biological sectors and in the health arena.<sup>82</sup>

## B. Eligibility Restrictions

### 1. Global Competition

As noted earlier, a few months after COVID-19 became a pandemic, India and South Africa submitted a proposal to the WTO to temporarily waive more than half of the provisions in the TRIPS Agreement to facilitate the “prevention, containment or treatment of COVID-19.”<sup>83</sup> By fall 2021, these coun-

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draft-genome-virus-implicated-wuhan-pneumonia-outbreak [https://perma.cc/4CYJ-U3H8] (reporting that “a consortium of [Chinese] researchers published a draft genome of the newly discovered coronavirus suspected of causing the outbreak”). See generally Jorge L. Contreras, *Pathogen Genomes as Global Public Goods (And Why They Should Not Be Patented)*, 55 N.Y.U. J. INT’L L. & POL. 533 (2023) (discussing why pathogen genomes should be treated as global public goods).

80. For discussions of China’s eagerness to develop soft power through the provision of aid and support to other developing countries, see generally JOSHUA KURLANTZICK, *CHARM OFFENSIVE: HOW CHINA’S SOFT POWER IS TRANSFORMING THE WORLD* (2007); THOMAS LUM ET AL., *CHINA’S “SOFT POWER” IN SOUTHEAST ASIA* (2008).

81. See Peter K. Yu, *Building Intellectual Property Infrastructure Along China’s Belt and Road*, 14 U. PA. ASIAN L. REV. 281, 319–21 (2019) [hereinafter Yu, *Belt and Road*] (discussing the potential for China to use the Belt and Road Initiative to foster transfer of technology to other members of the initiative).

82. See *supra* text accompanying notes 31–58 (discussing the changing landscape of pharmaceutical innovation in China).

83. *TRIPS Waiver Proposal*, *supra* note 5; *Revised TRIPS Waiver Proposal*, *supra* note 5. See generally Peter K. Yu, *A Critical Appraisal of the COVID-19 TRIPS Waiver*, in *INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE* (Taina E. Pihljarinne et al. eds., forthcoming 2023) (critically appraising the COVID-19 TRIPS waiver).

tries, along with their cosponsors and supporters,<sup>84</sup> realized that the proposal would be unlikely to receive enough support to achieve consensus within the WTO membership.<sup>85</sup> In December 2021, the European Union, India, South Africa, and the United States, with the support of the WTO Secretariat, launched their own consultations to find a compromise that could be potentially adopted at the Twelfth WTO Ministerial Conference (MC12) in Geneva in June 2022.<sup>86</sup>

Three months before the ministerial conference, a draft proposal was leaked.<sup>87</sup> Included in that proposal was a highly controversial footnote that limited the eligibility to any negotiated arrangement to “any developing country Member that [had] exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021.”<sup>88</sup> Because China accounted for slightly over a third of these exports by December 2021, according to the WTO-IMF COVID-19 Vaccine Trade Tracker,

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84. See Carlos M. Correa et al., *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements 1* (S. Ctr., Research Paper No. 135, 2021) (noting “the support of more than 100 countries as well as over 300 civil society organizations” and the cosponsorship of “64 countries from Asia, Africa and Latin America, including the African Group and the least developed countries (LDC) group”).

85. D. Ravi Kanth, *US, EU, India, South Africa Hold Talks on TRIPS Waiver Compromise*, TWN INFO SERV. ON WTO & TRADE ISSUES (Dec. 14, 2021), <https://www.twn.my/title2/wto.info/2021/ti211210.htm> [<https://perma.cc/823C-86ZE>] [hereinafter Kanth, *TRIPS Waiver Compromise*]. Those countries that the press had frequently reported as strongly opposing the waiver were the European Union, Switzerland, and the United Kingdom. See D. Ravi Kanth, *EU, Switzerland, UK Continue Opposition, amid Support for TRIPS Waiver*, TWN INFO SERV. ON WTO & TRADE ISSUES (Sept. 16, 2021), <https://www.twn.my/title2/wto.info/2021/ti210913.htm> [<https://perma.cc/M3XS-2YDT>] (reporting that “the European Union led by Germany, Switzerland, and the United Kingdom . . . seem determined to undermine an expeditious decision on the temporary waiver for combating the COVID-19 pandemic”); see also Ashleigh Furlong et al., *Who Killed the COVID Vaccine Waiver?*, POLITICO (Nov. 10, 2022), <https://www.politico.eu/article/covid-vaccine-poor-countries-waiver-killed/> [<https://perma.cc/KEA5-T3P6>] (providing an investigative report on the lobbying against the COVID-19 TRIPS waiver).

86. Kanth, *TRIPS Waiver Compromise*, *supra* note 85.

87. See Ed Silverman, *A Compromise Is Reached on an Intellectual Property Waiver for Covid-19 Vaccines, but Does It Go Far Enough?*, STAT NEWS (Mar. 15, 2022), <https://www.statnews.com/pharmalot/2022/03/15/covid19-vaccine-patents-wto/> [<https://perma.cc/RN5A-XU4D>] (providing the leaked text).

88. *TRIPS COVID-19 Solution*, ¶ 1 n.1, <https://freepdfhosting.com/4d79fc6c70.pdf> [<https://perma.cc/D7FP-7BN5>] (last visited Mar. 20, 2022).

the country was de facto the only developing economy that would have been disqualified for any negotiated arrangement.<sup>89</sup>

While this footnote was undeniably undiplomatic, it is not difficult to understand the position taken by the drafters of the proposal, especially from a global competition standpoint. Even though China remains a middle-income country on a per capita basis, it has in the aggregate the world's second largest or largest economy, depending on whether the country's gross national income is calculated based on purchasing power parity (PPP) estimates.<sup>90</sup> China also accounts for about a third of the world's exports of COVID-19 vaccine doses.<sup>91</sup> In these circumstances, many WTO delegates understandably took the position that a country with such economic power and export capacity did not deserve special arrangements provided by the negotiated compromise. The denial of such arrangements also resonated well with the position taken by the United States and other developed countries concerning the need to curtail the special and differential treatment enjoyed by developing countries in the WTO.<sup>92</sup>

Moreover, it is unclear whether China would need or want the arrangements provided by the negotiated compromise, considering the commercial success its vaccine manufacturers had already achieved. As noted earlier, COVAX entered into an agreement to purchase hundreds of millions of doses

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89. Yu, *China, the TRIPS Waiver*, *supra* note 8.

90. *Compare GDP (Current US\$)*, WORLD BANK, [https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?most\\_recent\\_value\\_desc=true](https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?most_recent_value_desc=true) [<https://perma.cc/736D-B35E>] (last visited Nov. 6, 2022), *with GDP, PPP (current international \$)*, WORLD BANK, [https://data.worldbank.org/indicator/NY.GDP.MKTP.PP.CD?most\\_recent\\_value\\_desc=true](https://data.worldbank.org/indicator/NY.GDP.MKTP.PP.CD?most_recent_value_desc=true) [<https://perma.cc/HZ22-HWF2>] (last visited Nov. 6, 2022).

91. *WTO-IMF COVID-19 Vaccine Trade Tracker*, *supra* note 24.

92. See Gao, *supra* note 17, at 23 (“[W]hile developed countries have been willing to extend special and differential treatment to smaller developing countries, they are reluctant to extend the same treatment to large developing countries such as China which have become economic powerhouses in their own right.”); Sangeeta Shashikant, *Intense IP Negotiations Are Underway, Resolution on Eligibility Criteria Outstanding*, TWN INFO SERV. ON HEALTH ISSUES (June 16, 2022), <https://www.twn.my/title2/health.info/2022/hi220609.htm> [<https://perma.cc/7CV4-TMZ2>] (noting that “developed countries have persistently tried to limit the number of developing countries that may benefit from special and differential treatment in the WTO”).

of COVID-19 vaccines from Sinopharm and Sinovac.<sup>93</sup> Having derived substantial financial benefits from the international sale of COVID-19 vaccines, these companies would have strong incentives to lobby their government not to disrupt the international trading system, including through the waiver of TRIPS-based intellectual property rights.<sup>94</sup> Indeed, a month before MC12, China already announced at the General Council's meeting its intention not to use the proposed arrangements as long as the WTO membership agreed to drop the eligibility language that would single out China for exclusion.<sup>95</sup>

In sum, the eligibility restrictions found in the draft proposal that eventually formed the basis of the Ministerial Decision on the TRIPS Agreement (Ministerial Decision) at MC12 can be easily justified by the need to address global competition—whether from the standpoint of the United States or that of other developed countries. China's concerns about the potential for the eligibility restrictions to undermine its global competitive position in the future also explain its strong reaction.

## 2. *Global Health*

From a global health standpoint, however, restrictions that would make China ineligible for the negotiated compromise will greatly hinder the country's ability to supply health products and technologies to other parts of the world.<sup>96</sup> Because many health products and technologies are currently produced in China, and many developing countries still lack the needed technical and manufacturing capabilities,<sup>97</sup> China

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93. Hollingsworth, *supra* note 22.

94. See Yu, *Deferring Intellectual Property Rights*, *supra* note 61, at 519 (“If adopted, the waiver would have undermined th[e] commercial activities [conducted by China-based Sinopharm and Sinovac].”).

95. D. Ravi Kanth, *China Offers “Positive Movement” on TRIPS COVID-19 Text at WTO*, TWN INFO SERV. ON WTO & TRADE ISSUES (May 12, 2022), <https://twn.my/title2/wto.info/2022/ti220512.htm> [https://perma.cc/V68Q-QEQV].

96. See Yu, *Deferring Intellectual Property Rights*, *supra* note 61, at 519 (noting that developing countries need other WTO members to export COVID-19 products and technologies).

97. See Mercurio, *WTO Waiver*, *supra* note 61, at 15–16 (considering “production capabilities and capacity . . . a major stumbling block in distributing medicines and vaccines”); Hilty et al., *supra* note 61, at 1 (noting that the

will remain an important supplier of health products and technologies to these countries. The continuous production and distribution of its products will certainly be important to the global effort to combat COVID-19.

More than two decades ago, WTO members faced similar challenges concerning inadequate therapeutic treatments for HIV/AIDS, tuberculosis, and malaria in Sub-Saharan Africa.<sup>98</sup> To foster access to the needed treatments, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in November 2001.<sup>99</sup> Paragraph 6 specifically recognized that “WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”<sup>100</sup> That paragraph became the basis for the adoption of the August 30, 2003 decision of the Council for Trade-Related Aspects of Intellectual Property Rights,<sup>101</sup> which was later formalized as a proposal for a new Article 31*bis* of the TRIPS Agreement.<sup>102</sup> Although the ratification of this amendment took more than a decade, countries with no or limited manufacturing capacity can now

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holdups in vaccine manufacturing and distribution have been caused in part by “insufficient production capacity and highly complex manufacturing process (in the case of mRNA and vector vaccines)”; Francis Gurry, *Some Considerations on Intellectual Property, Innovation, Access and COVID-19*, ¶ 10, WORLD INTEL. PROP. ORG. (Apr. 24, 2020), [https://www.wipo.int/about-wipo/en/dg\\_gurry/news/2020/news\\_0025.html](https://www.wipo.int/about-wipo/en/dg_gurry/news/2020/news_0025.html) [<https://perma.cc/D46A-HB9S>] (noting among the obstacles to the effective management of the COVID-19 crisis “the lack of relevant manufacturing capacity for needed medical equipment, such as ventilators and personal protective equipment”).

98. See World Trade Organization, *Declaration on the TRIPS Agreement and Public Health of 14 November 2001*, ¶ 1, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration] (“We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”). See generally THE GLOBAL GOVERNANCE OF HIV/AIDS: INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES (Obijiofor Aginam, John Harrington & Peter K. Yu eds., 2013) (collecting articles that discuss the access-to-medicines problems in relation to HIV/AIDS).

99. Doha Declaration, *supra* note 98.

100. *Id.* ¶ 6.

101. General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 (Sept. 1, 2003), 43 I.L.M. 509 (2004).

102. General Council, *Amendment of the TRIPS Agreement*, WTO Doc. WT/L/641 (Dec. 8, 2005).

import pharmaceutical products from eligible WTO members.<sup>103</sup>

When the August 30 decision was adopted, some developed and emerging countries agreed to opt out of the Article 31*bis* system. For instance, Australia, Canada, the European Communities (now the European Union), Iceland, Japan, New Zealand, Norway, Switzerland, and the United States agreed “not [to] use the system as importing Members.”<sup>104</sup> Chinese Taipei, Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Turkey, and the United Arab Emirates also agreed to use this system only in “situations of national emergency or other circumstances of extreme urgency.”<sup>105</sup> While it is understandable why the European Communities, Japan, the United States, and other high-income countries opted out of this system as importing members, such an approach was short-sighted from a global health standpoint. As Frederick Abbott and Jerome Reichman explain:

When the USA, European Union, Japan, Canada, Australia, Switzerland, among others, took themselves out of the equation as eligible importing countries under Article 31*bis*, they eliminated a large part of the potential global demand for pharmaceutical products originating from countries exporting under compulsory licenses. As a result, for example, if India were asked by countries in Africa and Latin America to manufacture drugs under compulsory license and export to them, the Indian producers might not be able to supply the [high-income countries] with the same products. The efficiencies in production that might otherwise be achieved by Indian manufacturing facilities when addressing a global market would be reduced. Giving effect to requested compulsory li-

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103. The proposed TRIPS amendment did not enter into effect until January 2017, after two-thirds of the WTO membership had ratified the amendment. See Press Release, World Trade Organization, WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines (Jan. 23, 2017), [https://www.wto.org/english/news\\_e/news17\\_e/trip\\_23jan17\\_e.htm](https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm) [<https://perma.cc/KJ8T-9DQH>].

104. TRIPS Agreement, *supra* note 4, Annex, ¶ 1(b) n.3.

105. Press Release, World Trade Org., Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005), [https://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](https://www.wto.org/english/news_e/pres05_e/pr426_e.htm) [<https://perma.cc/RJK7-A7YB>].

censes would thus become less cost-efficient and might result in higher selling prices for purchasers everywhere.<sup>106</sup>

In the early days of the COVID-19 pandemic, a consortium of nongovernmental organizations and individual experts called on countries that had previously opted out of the Article 31*bis* system to reconsider their earlier position.<sup>107</sup> It remains unclear whether those countries can now opt back into the system, but many commentators, myself included, take the position that countries should be allowed to do so.<sup>108</sup>

That these nongovernmental organizations and individual experts have called on the relevant countries to opt back into the Article 31*bis* system raises questions about the wisdom and benefits of eligibility restrictions seeking to remove China or other WTO members from the supply chain of health products and technologies. For developing countries lacking in capacity to develop or manufacture these products and technologies, having China as a potential supplier will be greatly beneficial, not to mention that the prices charged by Chinese manufacturers tend to be lower than those offered by their counterparts in the developed world.<sup>109</sup> To the extent that policymakers care about the development of a quick and effective global pandemic response, it would also be logical for them to support those international regulatory standards that

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106. Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535, 559 (2020).

107. See James Love, *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country, Under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INT'L (Apr. 7, 2020), <https://www.keionline.org/32707> [<https://perma.cc/3RTG-YEAY>] (reproducing the open letter).

108. See, e.g., Abbott & Reichman, *supra* note 106, at 559–60 (outlining the various legal approaches under which countries that had previously opted out may consider opting back in or otherwise making use of the Article 31*bis* system to import needed pharmaceutical products).

109. See generally ALEXANDRA HARNEY, *THE CHINA PRICE: THE TRUE COST OF CHINESE COMPETITIVE ADVANTAGE* (2008) (discussing the low prices for Chinese manufactures, its hidden costs, and its implications for the international community). *But see* SHAUN REIN, *THE END OF CHEAP CHINA: ECONOMIC AND CULTURAL TRENDS THAT WILL DISRUPT THE WORLD* (2014) (discussing how China's position as a low-cost producer is slowly coming to an end).

actively enhance access to health products and technologies regardless of the country of origin.

### C. *Public-Sector Participation*

#### 1. *Global Competition*

In the past few years, the United States and other developed countries have heavily criticized China's economic model, which requires the active and substantial participation of the public sector<sup>110</sup> and the practice of what commentators have labelled "state capitalism."<sup>111</sup> For instance, in July 2018, the United States submitted a paper to the WTO condemning what it called a "trade-disruptive economic model."<sup>112</sup> In academic literature, Mark Wu also published a highly influential article explaining why China's rise and sui generis economic structure have posed a major challenge to the WTO and its dispute settlement process.<sup>113</sup> Petros Mavroidis and André Sapir further discussed why China violates the spirit, but not necessarily the letter, of WTO rules:

China does not violate WTO rules more than any other WTO member. And when it is told by WTO judges that it has violated international rules, it takes appropriate measures to correct its domestic rules. Yet, because of its idiosyncratic economic system, China clearly violates the spirit of the WTO, which was not conceived to have a socialist country as one of its largest members, and now also the world's largest goods exporter.<sup>114</sup>

Based on these analyses, one can see why the government-driven model that China currently embraces has created

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110. For discussions of China's economic model, see generally PETROS C. MAVROIDIS & ANDRÉ SAPIR, *CHINA AND THE WTO: WHY MULTILATERALISM STILL MATTERS* (2021); Gao, *supra* note 17; Rob Howse, *Official Business: International Trade Law and the Resurgence (or Resilience) of the State as an Economic Actor*, 43 U. PA. J. INT'L L. 821 (2022); Lee, *supra* note 17; Mark Wu, *The "China, Inc." Challenge to Global Trade Governance*, 57 HARV. INT'L L.J. 261 (2016).

111. E.g., Curtis J. Milhaupt & Wentong Zheng, *Beyond Ownership: State Capitalism and the Chinese Firm*, 103 GEO. L.J. 665 (2015).

112. Communication from the United States, *China's Trade-Disruptive Economic Model*, WTO Doc. WT/GC/W/745 (July 16, 2018).

113. Wu, *supra* note 110.

114. MAVROIDIS & SAPIR, *supra* note 110, at viii.

problems in the international trading system, especially from the developed countries' perspective. Because companies in these countries are accustomed to conducting business under a drastically different economic model, the Chinese economic model would put U.S. and other companies at a competitive disadvantage. In the health arena, U.S. politicians and commentators have also expressed deep concern about the United States' continuous and increasing dependence on Chinese pharmaceutical products and ingredients.<sup>115</sup>

From a global competition standpoint, it would be logical to develop new international regulatory standards that would undermine, if not outlaw, China's economic model.<sup>116</sup> Those standards would also help counteract China's active effort in exporting its model and experiences through the Regional

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115. See generally ROSEMARY GIBSON & JANARDAN PRASAD SINGH, *CHINA RX: EXPOSING THE RISKS OF AMERICA'S DEPENDENCE ON CHINA FOR MEDICINE* (2018) (warning about the increasing risks of the United States' growing dependence on the global supply chain for pharmaceutical products and vitamins on the APIs originating in China); 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> [<https://perma.cc/4Y8Q-VRC2>] ("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/> [<https://perma.cc/F8BR-MXBC>] ("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.").

116. Such development already exists. A key goal behind the United States' negotiations for the Trans-Pacific Partnership is to develop solutions to address problems raised by the Chinese economic model. As President Barack Obama declared at the negotiations' conclusion in Atlanta: "When more than 95 percent of our potential customers live outside our borders, we can't let countries like China write the rules of the global economy. We should write those rules, opening new markets to American products while setting high standards for protecting workers and preserving our environment." *Statement by the President on the Trans-Pacific Partnership*, WHITE HOUSE (Oct. 5, 2015), <https://obamawhitehouse.archives.gov/the-press-office/2015/10/05/statement-president-trans-pacific-partnership> [<https://perma.cc/R5SM-3HHQ>].

Comprehensive Economic Partnership (RCEP),<sup>117</sup> the Belt and Road Initiative,<sup>118</sup> and other international endeavors.

## 2. *Global Health*

From a global health standpoint, however, the analysis will be quite different. During the COVID-19 pandemic, governments in developed and emerging countries poured in considerable resources to support research and development.<sup>119</sup> As Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang, and Graham Dutfield recount:

The global public sector has spent at least €93 billion on the development of COVID-19 vaccines and therapeutics—including over €88 billion on vaccines. Detailed analysis shows that public funding accounted for 97–99.0 per cent of the funding towards the R&D of ChAdOx, the underlying technology of the Oxford-AZ vaccine. The Moderna vaccine, which is sometimes referred to as the NIH-Moderna vaccine due to co-inventorship by [National Institutes of Health] scientists, was almost entirely funded by the US government, which provided \$10 billion. BioNTech is a spin-off company of the public Johannes Gutenberg-University Mainz and it received more than \$445 million from the German government.<sup>120</sup>

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117. Regional Comprehensive Economic Partnership Agreement, Nov. 15, 2020, <https://rcepsec.org/legal-text/> [<https://perma.cc/XRK2-8Q9Z>] [hereinafter RCEP Agreement].

118. For discussions of the Belt and Road Initiative 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); Yu, *Belt and Road*, *supra* note 81; Peter K. Yu, *China, "Belt and Road" and Intellectual Property Cooperation*, 14 GLOB. TRADE & CUSTOMS J. 244 (2019).

119. For discussions of the considerable public funding that U.S., European, and other governments have provided to vaccine manufacturers, see, for example, LAWRENCE O. GOSTIN, GLOBAL HEALTH SECURITY: A BLUEPRINT FOR THE FUTURE 202 (2021); E. Richard Gold, *What the COVID-19 Pandemic Revealed About Intellectual Property*, 40 NATURE BIOTECHNOLOGY 1428, 1428 (2022); Joseph & Dore, *supra* note 27, at 174; Siva Thambisetty et al., *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81 CAMBRIDGE L.J. 384, 391–92 (2022).

120. Thambisetty et al., *supra* note 119, at 391–92 (footnotes omitted); see also Gold, *supra* note 119, at 1428 (“Although companies played a critical role in vaccine and antiviral development, they financed their work through

Indeed, such outpouring of resources has been frequently used to explain why the incentive framework supported by intellectual property rights may not be needed in these special circumstances.<sup>121</sup> After all, governments around the world have exercised emergency powers to introduce measures to combat COVID-19 and to support the manufacturing of personal protective equipment, vaccines, therapeutics, and other essential products.<sup>122</sup> Immediately coming to mind is the United States' use of the Defense Production Act<sup>123</sup> during the pandemic.<sup>124</sup>

Moreover, a growing volume of academic literature has explained the need for and importance of alternative incentive frameworks in vaccine development. As Ana Santos Rutschman observes:

[I]n spite of the increasing burden posed by infectious diseases in the United States and abroad, the market for vaccines targeting emerging pathogens is often considered unprofitable. Globally, very few private companies currently engage in vaccine research and development . . . , and the public sector currently lacks the capacity to fully develop and manufacture new vaccines on its own. While the rates of

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the prospect of large procurement contracts rather than the prospect of [intellectual property].”).

121. See *Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal* (London Sch. of Econ. & Pol. Sci., Policy Briefing No. 46, 2021) (advocating for the adoption of the COVID-19 TRIPS waiver and noting that “in light of the considerable public financing of COVID-19 vaccine research, development, production and purchase, claims of inviolability of private [intellectual property] monopoly rights cannot be justified”).

122. See generally ASSESSING LEGAL RESPONSES TO COVID-19, at 7–53 (Scott Burris et al. eds., 2020) (collecting essays that discuss the use of government powers to control the COVID-19 pandemic); ALAN GREENE, EMERGENCY POWERS IN A TIME OF PANDEMIC (2020) (discussing the use of emergency powers during the COVID-19 pandemic).

123. Defense Production Act of 1950, Pub. L. No. 81-774, 64 Stat. 798 (codified as amended at 50 U.S.C. §§ 4501–4568).

124. See, e.g., Ana Swanson et al., *Trump Seeks to Block 3M Mask Exports and Grab Masks from Its Overseas Customers*, N.Y. TIMES (Apr. 6, 2020), <https://www.nytimes.com/2020/04/03/us/politics/coronavirus-trump-3m-masks.html> [<https://perma.cc/5SLH-AXLQ>] (reporting that “the administration is invoking the [Defense Production Act] to compel 3M to send to the United States masks made in factories overseas and to stop exporting masks the company manufactures in the United States”).

vaccine-related patent applications increased, over time the number of new vaccines entering the market each year has remained relatively low.<sup>125</sup>

Xue Qiwei Claire and Lisa Larrimore Ouellette also declare: “[A]bsent significant government intervention in healthcare markets—such as mandatory or free vaccination—the prospect of monopoly profits will under-incentivize the development of vaccines relative to treatments. In particular, traditional market-based [intellectual property] incentives may be specifically insufficient for promoting vaccine development, despite the outsized social benefits of vaccines.”<sup>126</sup>

Amid the COVID-19 pandemic, the U.N. Committee on Economic, Social and Cultural Rights released its long-awaited general comment on the right to enjoy the benefits of scientific progress and its applications.<sup>127</sup> Paragraph 62 specifically provides: “States should provide adequate financial support for research that is important for the enjoyment of economic, social and cultural rights, either through national efforts or, if necessary, by resorting to international and technical cooperation.”<sup>128</sup> This recommendation is consistent with the Committee’s earlier authoritative comment on the right to health, which obliges state parties to “to use the maximum of its available resources for the realization of [that] right.”<sup>129</sup>

In its latest *World Intellectual Property Report*, WIPO also underscores the important role government policy can play in

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125. Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 731 (2019).

126. Xue Qiwei Claire & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIENCES 1, 7 (2020) (footnote omitted).

127. Committee on Economic, Social and Cultural Rights, *General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights (Article 15(1)(b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights)*, U.N. Doc. E/C.12/GC/25 (Apr. 30, 2020) [hereinafter *General Comment No. 25*]. See generally Peter K. Yu, *Can the Right to Science Reduce the Tensions Between Intellectual Property and Human Rights?*, in A HUMAN-CENTERED APPROACH TO HEALTH INNOVATIONS: RECONCILING INTELLECTUAL PROPERTY WITH HUMAN RIGHTS (Lisa Biersay, Thomas Pogge & Peter K. Yu eds., forthcoming 2024).

128. *General Comment No. 25*, *supra* note 127, ¶ 62.

129. Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)*, ¶ 47, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

setting the direction of innovation, especially when confronted with “‘grand challenges,’ such as global warming and future pandemics.”<sup>130</sup> As the report declares:

Government policies and the innovation decisions made by private companies coexist in a complex innovation ecosystem that includes individuals—such as scientists—government agencies and multinational companies, among others. Government and private companies can complement each other or otherwise compete for the limited resources devoted to innovation. In either case, they are continuously influencing one another.<sup>131</sup>

The report states further that “when the needs of society and the goals of for-profit private companies are misaligned, governments can, and probably should, step in.”<sup>132</sup> Such intervention is particularly desirable “when the social returns to or benefits from addressing society’s needs . . . far outweigh the private returns to continuing with business as usual.”<sup>133</sup>

Given the positions taken by intergovernmental bodies, policymakers, and individual experts, a model that supports active public-sector participation in the development of health products and technologies seems well justified from a global health standpoint.<sup>134</sup> To the extent that policymakers are eager to develop a response that would effectively combat the next pandemic, they will need to introduce new international regulatory standards that would take advantage of such participation. Those standards will be consistent with the resolution adopted by the U.N. General Assembly in the early days of the COVID-19 pandemic, which “[e]ncourage[d] Member States to work in partnership with all relevant stakeholders to in-

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130. WORLD INTELL. PROP. ORG., WORLD INTELLECTUAL PROPERTY REPORT 2022: THE DIRECTION OF INNOVATION 15 (2022).

131. *Id.*

132. *Id.* at 78.

133. *Id.*

134. There are nonetheless trade-related arguments against such participation, including those relating to inappropriate state subsidies. *See supra* text accompanying notes 112–14 (providing critiques of China’s reliance on active and substantial public-sector participation in its economic model).

crease research and development funding for vaccines and medicines.”<sup>135</sup>

#### IV. TAKEAWAYS

The previous Part discusses the “China dilemma” confronting policymakers during the inter-pandemic period and in the post-COVID-19 era. This Part identifies four key takeaways that can be drawn from that discussion. These takeaways will not only improve the understanding of the challenges and complications China has posed, or will pose, to policymakers seeking to develop new international regulatory standards, but will also help develop strategies that would improve global pandemic preparedness in the international regulatory system.

##### A. *Dual Roles*

This Article has shown that China can play important roles in the promotion of global public health. What contributions it makes and what complications it creates will depend on one’s perspective. To some extent, the debate about China’s role in the global health arena brings to mind the oft-invoked “glass half full, glass half empty” metaphor.<sup>136</sup> Whether the glass is half full or half empty, the perspective is necessarily incomplete and therefore not conducive to sound policymaking. A holistic assessment, by contrast, will enrich the understanding of China’s role in the global health arena—both present and future. It will also help locate solutions that will take full advantage of the country’s contributions while avoiding the attendant complications and challenges.

When assessing China’s role in the global health arena, policymakers and commentators should take into account China’s unique approaches in this arena. Unlike the United States and other developed countries, China has a strong pref-

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135. G.A. Res. 74/274, International Cooperation to Ensure Global Access to Medicines, Vaccines and Medical Equipment to Face COVID-19, ¶ 3 (Apr. 20, 2020).

136. See Peter K. Yu, *The Long and Winding Road to Effective Copyright Protection in China*, 49 PEPP. L. REV. 681, 728 (2022) (“Those handling China policies are always confronted with the challenge of determining ‘whether the proverbial glass is half full or half empty.’” (quoting Peter K. Yu, *Editorial*, 8 QUEEN MARY J. INTELL. PROP. 1, 1 (2018))).

erence for bilateral approaches.<sup>137</sup> Much to the disappointment of its developing country allies and the supportive non-governmental organizations, China did not join COVAX until October 2020, six months after the launch of the initiative.<sup>138</sup> A recent study on China's pandemic diplomacy shows that such diplomacy "was most significant in countries where China already had strong diplomatic relations and sizable influence before the start of the pandemic,"<sup>139</sup> such as members of the Belt and Road Initiative.<sup>140</sup> In areas such as international trade and public health, China has also emphasized active and substantial public-sector participation.<sup>141</sup> While many countries

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137. See China Power Team, *supra* note 25 (noting China's preference for bilateral approaches).

138. Hemant Adlakha, *Did China Join COVAX to Counter or Promote Vaccine Nationalism?*, THE DIPLOMAT (Oct. 23, 2020), <https://thediplomat.com/2020/10/did-china-join-covax-to-counter-or-promote-vaccine-nationalism/> [<https://perma.cc/QG6Y-SYBP>]; Colin Qian & Stephanie Nebehay, *China Joins WHO-Backed Vaccine Programme COVAX Rejected by Trump*, REUTERS (Oct. 8, 2020), <https://www.reuters.com/article/us-health-coronavirus-china-covax/china-joins-who-backed-vaccine-programme-covax-rejected-by-trump-idUSKBN26U027> [<https://perma.cc/LB6Y-AF6C>]. The United States did not join COVAX until after the arrival of the Biden Administration. Stephanie Nebehay, *U.S., Staying in WHO, to Join COVID Vaccine Push for Poor Nations: Fauci*, REUTERS (Jan. 21, 2021), <https://www.reuters.com/article/us-health-coronavirus-who-usa/u-s-staying-in-who-to-join-covid-vaccine-push-for-poor-nations-fauci-idUSKBN29Q12B> [<https://perma.cc/NN6E-74NE>].

139. China Power Team, *supra* note 25.

140. Catching considerable attention during the COVID-19 pandemic is the concept of "Health Silk Road." See Yu, *China, the TRIPS Waiver*, *supra* note 8 (discussing this concept); see also China Power Team, *supra* note 25 (noting that "countries that have signaled their endorsement of [this] concept scored much higher" in terms of the scope and impact of China's activities during the COVID-19 pandemic). As noted in a joint statement released in June 2020, China will work with other countries to "support mutual efforts in combating the COVID-19, and [to] cooperate to address, control and overcome the pandemic through the sharing of timely and necessary information, experiences and best practices for diagnosis and treatment of the COVID-19, strengthening and upgrading the capacity of public health system, promoting joint scientific research and international dialogues among health professionals, and providing assistance to countries in need." *Joint Statement of the High-level Video Conference on Belt and Road International Cooperation: Combating COVID-19 with Solidarity*, MINISTRY OF FOREIGN AFFS. OF THE PEOPLE'S REPUBLIC OF CHINA (June 19, 2020), [https://www.fmprc.gov.cn/mfa\\_eng/wjdt\\_665385/2649\\_665393/202006/t20200619\\_679632.html](https://www.fmprc.gov.cn/mfa_eng/wjdt_665385/2649_665393/202006/t20200619_679632.html) [<https://perma.cc/L2KJ-P579>].

141. See *supra* Part III.C (discussing the reliance on public-sector participation in the Chinese economic model).

have taken similar approaches during the COVID-19 pandemic, China will likely continue this emphasis even long after the pandemic.

### B. *Framing*

Part III shows vividly how the outcome of the analysis can be drastically different depending on whether the debate is framed in terms of global competition or global health. The importance of framing is widely discussed in intellectual property and international negotiation literature. For example, John O'Dell and Susan Sell explain how framing can help build an effective coalition on intellectual property and public health in the WTO.<sup>142</sup> John Braithwaite and Peter Drahos concur: "Had TRIPS been framed as a public health issue, the anxiety of mass publics in the US and other Western states might have become a factor in destabilizing the consensus that US business elites had built around TRIPS."<sup>143</sup> In addition, Amy Kapczynski discusses the importance of frame mobilization to the Access to Knowledge Movement.<sup>144</sup> By emphasizing inequities and injustices generated by inappropriate protection of intellectual property rights,<sup>145</sup> the movement's proponents successfully invoked "access to knowledge" as a common frame "to build support, recruit allies, and exert political leverage."<sup>146</sup>

During the negotiations at MC12 in the run-up to the adoption of the Ministerial Decision,<sup>147</sup> which the WTO membership ultimately adopted in lieu of the COVID-19 TRIPS

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142. John S. Odell & Susan K. Sell, *Reframing the Issue: The WTO Coalition on Intellectual Property and Public Health, 2001*, in *NEGOTIATING TRADE: DEVELOPING COUNTRIES IN THE WTO AND NAFTA 85* (John S. Odell ed., 2006).

143. JOHN BRAITHWAITE & PETER DRAHOS, *GLOBAL BUSINESS REGULATION* 576 (2000).

144. Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 *YALE L.J.* 804 (2008).

145. See Gaëlle Krikorian, *Access to Knowledge as a Field of Activism*, in *ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY* 57, 69 (Gaëlle Krikorian & Amy Kapczynski eds., 2010) ("[T]he term 'access to knowledge' emerged as a common umbrella under which individuals and organizations could denounce inequalities and injustices related to intellectual property.").

146. Kapczynski, *supra* note 144, at 851.

147. World Trade Organization, *Ministerial Decision on the TRIPS Agreement*, WTO Doc. WT/MIN(22)/30 (June 22, 2022) [hereinafter Ministerial Deci-

waiver, it was unclear whether the membership would be willing to prioritize efforts to combat the global pandemic and adjust WTO trade rules accordingly. As Bryan Mercurio laments:

If expanding access to vaccines is the purpose of the agreement, one would think that . . . it would make sense for restrictions on importing members but not for exporting members. At an NGO briefing session held during the ministerial conference, WTO Director-General Okonjo-Iweala seemed to imply that industrial policy was as important for health as she “justif[ied] this outcome on the grounds that it would be desirable protectionism to achieve the objective of promoting vaccine manufacturing capacity in Africa and other developing countries.” This response is curious, as it implies industrial policy rather than health was a key determinant for the restriction (and perhaps, the agreement).<sup>148</sup>

Indeed, the Ministerial Decision adopted at the end of MC12 strongly suggests that the WTO continues to prioritize industrial policy over public health. Despite the developing countries’ demand for a broad COVID-19 TRIPS waiver, the adopted compromise was narrowly confined to vaccines and patents and provided only very limited adjustments to TRIPS obligations.<sup>149</sup>

### C. *Interrelationship*

The earlier discussion of the COVID-19 TRIPS waiver, the Ministerial Decision, and China’s global pandemic response has made salient the strong inter-relationship between different international regulatory standards, whether in the area of international trade, intellectual property, or public health. Al-

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sion]. See generally Yu, *Ministerial Decision*, *supra* note 73 (discussing the Ministerial Decision).

148. Bryan Mercurio, *Sharpening the Tools in the Pandemic-Ending Toolbox*, THINK GLOBAL HEALTH (June 23, 2022), <https://www.thinkglobalhealth.org/article/sharpening-tools-pandemic-ending-toolbox> [https://perma.cc/H5JF-6LQ7].

149. Compare Ministerial Decision, *supra* note 147, with *Revised TRIPS Waiver Proposal*, *supra* note 5.

though the WTO Appellate Body<sup>150</sup> and WTO panels have repeatedly stated that WTO agreements should not be viewed in clinical isolation from each other,<sup>151</sup> these bodies have yet to fully embrace this cross-cutting approach. In fact, commentators have widely criticized their decisions at the intersection of intellectual property and public health.<sup>152</sup>

One interesting development in the past decade concerns the emergence of megaregulatory standards—a topic to which Benedict Kingsbury, Rochelle Dreyfuss, and their colleagues have devoted considerable attention.<sup>153</sup> Both the Trans-Pacific

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150. See, e.g., Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, at 17, WTO Doc. WT/DS2/AB/R (adopted Apr. 29, 1996) (declaring that “the General Agreement [which consists of agreements in many different areas] is not to be read in clinical isolation from public international law”).

151. See, e.g., Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 7.19, WT/DS50/R (Sept. 5, 1997) (recognizing that the TRIPS Agreement “is an integral part of the WTO system, which itself builds upon the experience over nearly half a century” under the General Agreement on Tariffs and Trade); see also Marrakesh Agreement Establishing the World Trade Organization art. II(2), Apr. 15, 1994, 1867 U.N.T.S. 154 (“The agreements and associated legal instruments included in Annexes 1, 2 and 3 [including the TRIPS Agreement in Annex 1C] are integral parts of this Agreement, binding on all Members.”).

152. See, e.g., Rochelle C. Dreyfuss, *Hedging Bets with BITS: The Impact of Investment Obligations on Intellectual Property Norms*, in GLOBAL INTELLECTUAL PROPERTY PROTECTION AND NEW CONSTITUTIONALISM: HEDGING EXCLUSIVE RIGHTS 157, 160 (Jonathan Griffiths & Tuomas Mylly eds., 2021) (criticizing the WTO panel in *Canada—Patent Protection of Pharmaceutical Products* for failing to “directly consider[r] the public welfare goals that Canada was seeking to promote”); Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. WORLD INTELL. PROP. 493, 496 (2000) (criticizing the same WTO panel for being “only interested in how much the rights holder might lose, not in how much society might gain, from a given exception”).

153. See generally MEGAREGULATION CONTESTED: GLOBAL ECONOMIC ORDERING AFTER TPP (Benedict Kingsbury et al. eds., 2019) [hereinafter MEGAREGULATION CONTESTED] (discussing the development of these standards); Rochelle Cooper Dreyfuss, *Harmonization: Top Down, Bottom Up—and Now Sideways? The Impact of the IP Provisions of Megaregional Agreements on Third Party States*, in MEGAREGULATION CONTESTED, *supra*, at 345 (discussing the development of megaregulation in the intellectual property context). Benedict Kingsbury and his coeditors defined megaregulation as “a novel form of inter-state economic ordering and regulatory governance on an extensive substantive and trans-regional scale.” Benedict Kingsbury et al., *Introduction: The Essence, Significance, and Problems of the Trans-Pacific Partnership*, in MEGAREGULATION CONTESTED, *supra*, at 1, 2.

Partnership (TPP) Agreement and the RCEP Agreement contain at least twenty chapters, covering different issue areas.<sup>154</sup> While the intellectual property chapters in these agreements have raised the intellectual property standards beyond what the TRIPS Agreement requires,<sup>155</sup> these megaregulatory regimes also include provisions supporting efforts to promote public health. A case in point is the incorporation of the Doha Declaration and Article 31*bis* in both the TPP and RCEP Agreements.<sup>156</sup> Article 11.40 of the RCEP Agreement also allows for the experimental use of a patent so long as such use is consistent with the patent exceptions allowed under Article 11.38.<sup>157</sup>

While the inclusion of treaty language to support efforts to promote public health remains promising, it is unclear how effective this language will be in megaregulatory regimes.<sup>158</sup> After all, those charged with dispute settlement tend to take a conservative approach and focus narrowly on the chapter at

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154. Trans-Pacific Partnership Agreement, Feb. 4, 2016, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> [<https://perma.cc/4RA4-A22K>]; RCEP Agreement, *supra* note 117. The TPP Agreement has since evolved into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) following the United States' withdrawal. Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Mar. 8, 2018, <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> [<https://perma.cc/6LUH-F7S5>].

155. See generally Peter K. Yu, *The Non-multilateral Approach to International Intellectual Property Normsetting*, in *INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH* 83 (Daniel J. Gervais ed., 2015) (discussing the TRIPS-plus standards in the TPP Agreement and other nonmultilateral intellectual property agreements); Peter K. Yu, *The RCEP and Trans-Pacific Intellectual Property Norms*, 50 *VAND. J. TRANSNAT'L L.* 673, 704–31 (2017) (discussing the draft provisions in the RCEP intellectual property chapter).

156. RCEP Agreement, *supra* note 117, art. 11.8 (“The TRIPS Agreement and Public Health”); Trans-Pacific Partnership Agreement, *supra* note 154, art. 18.6 (“Understandings Regarding Certain Public Health Measures”).

157. RCEP Agreement, *supra* note 117, art. 11.40; see also Vitor Henrique Pinto Ido, *TRIPS Flexibilities and TRIPS-Plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space Is Retained?* 17–18 (S. Ctr., Research Paper No. 131, 2021) (discussing this provision).

158. See generally *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES* (Pedro Roffe et al. eds., 2006) (collecting articles that discuss access-to-medicines problems in relation to the TRIPS Agreement).

issue,<sup>159</sup> such as the intellectual property chapter in a state-to-state dispute involving intellectual property rights. It can therefore be challenging for public health-supporting language to find its way to the dispute settlement process.

#### D. *An Uncertain Future*

Although the past two decades have seen the proliferation of bilateral, regional, and plurilateral agreements, including those with megaregulatory standards, it is unclear whether such proliferation will continue after the COVID-19 pandemic. For instance, commentators already wonder whether countries will opt for more regional negotiations, as opposed to multilateral negotiations, given the disruption caused by the pandemic.<sup>160</sup> In the first few months of 2020, the Association of Southeast Asian Nations (ASEAN) moved ahead of the European Union to become China's top trading partner.<sup>161</sup> Its ascendance suggests the growing appeal and viability of a regional approach.

Another issue that directly relates to this Article concerns the ongoing economic and technological rivalry between

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159. See Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 AM. U. L. REV. 829, 857–58 (2017) (criticizing arbitrators involved in resolving investor-state disputes in the intellectual property area for “focus[ing] narrowly on only the intellectual property side of the investment bargain . . . [and] ignor[ing] the existence of concessions outside the intellectual property field, such as free lands, tax breaks, exemption from export custom duties, and preferential treatment on foreign exchange”).

160. See, e.g., *Council of Councils Thirteenth Regional Conference: Insights from a Council of Councils Conference*, COUNCIL ON FOREIGN RELS. (Jan. 5, 2023), <https://www.cfr.org/report/council-councils-thirteenth-regional-conference> [<https://perma.cc/6EHV-Y3YB>] (“As geopolitical tensions increase, multilateral negotiations stall, and globalization weakens, regional economic initiatives can boost economic growth and foster and build on consensus in areas such as rules of origin, ecommerce, environmental goods, and services, and eventually expand those best practices at the multilateral level.”).

161. Ayman Falak Medina, *ASEAN Overtakes EU to Become China's Top Trading Partner in Q1 2020*, ASEAN BRIEFING (May 15, 2020), <https://www.aseanbriefing.com/news/asean-overtakes-eu-become-chinas-top-trading-partner-q1-2020/> [<https://perma.cc/RQ73-2TYN>]. Before the U.S.-China trade war in 2018, ASEAN was behind the United States as well. See *id.* (“ASEAN had already become China's second largest trading partner in 2019 with trade valued at US\$644 billion, overtaking the US amid friction between the world's largest economies.”).

China and the United States.<sup>162</sup> The current trade war between the two countries began in March 2018, when the Trump Administration announced its plan to impose trade tariffs on Chinese goods in the areas of aerospace, information communication technology, and machinery.<sup>163</sup> By the end of that Administration, the United States had imposed tariffs on more than \$500 billion worth of Chinese goods.<sup>164</sup> Meanwhile, China had imposed retaliatory tariffs on close to \$200 billion worth of U.S. goods.<sup>165</sup> Even though the Biden Administration has not yet introduced new tariffs, it is unlikely that the trade war will end any time soon. It also remains to be seen whether U.S.-China relations will improve or further deteriorate following the Twentieth Congress of the Chinese Communist Party, during which a group of hardline leaders were selected to join President Xi Jinping.<sup>166</sup>

Finally, just as this Article entered production, China relaxed its zero-COVID policy, which was adopted since the early days of the global pandemic.<sup>167</sup> It remains to be seen what ramifications this policy change will have on China's efforts in the public health arena, including its global pandemic response. It will also be interesting to see whether the changing policies will alter the discourse on Chinese vaccines, especially after the government began granting regulatory approvals to foreign mRNA or adenovirus vaccines,<sup>168</sup> or if it adopts new

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162. See *supra* note 17 (collecting sources that discuss U.S.-China economic and technological rivalry).

163. See Wong & Koty, *supra* note 63 (providing a timeline of the tariffs that China and the United States have imposed as part of the trade war).

164. Yu, *Trade Wars*, *supra* note 17, at 278.

165. *Id.*

166. Simone McCarthy et al., *Xi Jinping Enters Third Term as China's Most Powerful Leader in Decades Surrounded by Loyalists*, CNN (Oct. 23, 2022, 4:41 AM), <https://www.cnn.com/2022/10/22/china/china-party-congress-xi-jinping-leadership-lineup-revealed-intl-hnk/index.html> [<https://perma.cc/KLY8-D3E8>].

167. See Simone McCarthy, *As China Moves away from Zero-Covid, Health Experts Warn of Dark Days Ahead*, CNN (Dec. 7, 2022, 8:10 PM), <https://www.cnn.com/2022/12/06/china/china-zero-covid-relaxation-crisis-intl-hnk-mic/index.html> [<https://perma.cc/QJ2J-L6R6>] (reporting China's relaxation of its zero-COVID policy).

168. See Nicholas Gordon, *China Finally Approves an mRNA COVID Vaccine—but Only for Some Foreigners*, FORTUNE (Dec. 12, 2022 12:56 AM), <https://fortune.com/2022/12/12/china-approves-biontech-pfizer-mrna-covid-vaccine-restrictions/> [<https://perma.cc/7AY6-BHA4>] (“[China] would let Ger-

policies to accelerate the development of home-grown vaccines using novel technologies. All of these observations and questions point to an uncertain future.

## V. CONCLUSION

The COVID-19 pandemic has created an opportunity to review whether the existing international regulatory standards at the intersection of intellectual property, international trade, and public health are equipped to address a global pandemic. If over six million human lives lost and more than tens of trillions of dollars in economic damage are what we find on the report card, the answer to this question must be a resounding no. During the inter-pandemic period and in the post-COVID-19 era, we will need to consider the development of new international regulatory standards that would enable us to respond more effectively to the next pandemic.

A major dilemma confronting policymakers seeking to develop these new standards concerns the role of China. Because the country can be both a potential rival from a global competition standpoint and an important ally from a global health standpoint, how countries engage with China and what international regulatory standards they forge collectively will be an important topic in the years to come. Although this Article does not have space to provide a full exploration of the “China dilemma” or to advance some preliminary recommendations, it highlights the emerging challenges and complications that would impede our effort to improve global pandemic preparedness in the international regulatory system. Figuring out how to resolve this “China dilemma” will be critical to removing some of these impediments.

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man nationals receive the BioNTech COVID vaccine, which uses mRNA technology, in exchange for German health authorities . . . approving China’s Sinovac jab for Chinese nationals living in Germany.”).