



SCHOOL OF LAW
TEXAS A&M UNIVERSITY

Texas A&M Journal of Property
Law

Volume 7
Number 1 *Fall 2019 Symposium Edition*
Pharmaceutical Innovation, Patent Protection,
and Regulatory Exclusivities

Article 1

2-9-2021

Modalities, Challenges, and Possibilities: An Introduction to the Pharmaceutical Innovation Symposium

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Recommended Citation

Peter Yu, *Modalities, Challenges, and Possibilities: An Introduction to the Pharmaceutical Innovation Symposium*, 7 *Tex. A&M J. Prop. L.* 1 (2021).

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**MODALITIES, CHALLENGES, AND POSSIBILITIES: AN
INTRODUCTION TO THE PHARMACEUTICAL INNOVATION
SYMPOSIUM**

Peter K. Yu^{*}

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I. INTRODUCTION

On October 25, 2019, the *Texas A&M Journal of Property Law* and the Center for Law and Intellectual Property at Texas A&M University School of Law jointly organized the “Pharmaceutical Innovation, Patent Protection, and Regulatory Exclusivities” Symposium.¹ Although none of the organizers and participants could predict what was to come in the next few months,² there was a wide

DOI: <https://doi.org/10.37419/JPL.V7.I1.1>

^{*} Copyright © 2021 Peter K. Yu. Regents Professor of Law and Communication and Director, Center for Law and Intellectual Property, Texas A&M University. Part III of this Article was presented at the “Pharmaceutical Innovation, Patent Protection, and Regulatory Exclusivities” Symposium at Texas A&M University School of Law. The Article draws on research the Author conducted for earlier articles in the *Florida State University Law Review* and the *University of the Pacific Law Review*. The Author is grateful to Saurabh Vishnubhakat and the past and present members of the *Texas A&M Journal of Property Law*, in particular Jessica Bonds, Cameron Saenz, Katlyn Humbarger, Karina Rios, Christian Martinez, and Karen Alday for assistance in making this Symposium possible.

1. In addition to the four contributors to this special issue, the Symposium participants included Professors Gabriel Eckstein, Erika Lietzan, Glynn Lunney, Emily Morris, Arti Rai, John Thomas, and Saurabh Vishnubhakat.

2. It is worth noting that the public health community has made repeated calls for better pandemic preparedness since the outbreak of the Severe Acute Respiratory Syndrome (SARS). *See, e.g.*, THOMAS ABRAHAM, TWENTY-FIRST CENTURY PLAGUE: THE STORY OF SARS 140 (2007) (describing SARS as “a dress rehearsal

consensus that the rapid changes in the pharmaceutical landscape and our continuous struggle to strike a proper balance between proprietary protection and public access in the public health arena deserves scholarly, policy, and regulatory attention.

To help contextualize the articles included in this special issue and to inform readers about the inspirations and motivations behind the Symposium, Part II of this Introductory Article explores the different modalities of protection—in particular the role of patents and regulatory exclusivities in providing the needed incentives to pharmaceutical developers. Part III identifies three sets of challenges that affect the future of pharmaceutical innovation at both the domestic and international levels. Part IV utilizes a very recent event—the COVID-19 pandemic—to illustrate the wide array of policy options and possibilities both within and outside the intellectual property system. This Part makes salient the nexus between the domestic and international debates on pharmaceutical innovation.

II. MODALITIES

To provide pharmaceutical developers with the needed incentives, the intellectual property system grants two predominant forms of protection: patents and regulatory exclusivities. Patents provide pharmaceutical developers with limited protection to enable them to recoup the time, effort, and resources expended in research and development. Although critics of the patent system have

for the more serious threat posed by a new influenza pandemic”); 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 “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”); WORLD HEALTH ORG., AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS: PLAN OF ACTION 22 (2016), https://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf [<https://perma.cc/KR24-UNQL>] (including “[h]ighly pathogenic emerging coronaviruses relevant to humans” on the list of diseases that are “to be urgently addressed”). Every year, my university colleagues at the Scowcroft Institute of International Affairs at the Bush School of Government and Public Service hold a pandemic policy summit and publish a white paper on pandemic preparedness and response. See *Papers*, PANDEMIC & BIOSECURITY POL’Y PROGRAM, <https://bush.tamu.edu/scowcroft/programs/papers/> [<https://perma.cc/5B8Z-RSG2>] (collecting the white papers).

questioned this utilitarian justification,³ economists and other commentators have widely recognized the need to offer strong patent protection in the pharmaceutical and chemical sectors due to the significant risks and high research-and-development costs involved.⁴ It is therefore no surprise that the patent system has provided pharmaceutical products with longstanding protection, which can be traced back decades to the time when the synthetic dyestuff industry sought to protect its inventions.⁵

Unlike patents, regulatory exclusivities—in the form of either market or data exclusivities⁶—are of more recent origin. While such exclusivities vary from country to country, and at times go beyond intellectual property protection into the area of drug regulation, the international regime for market or data exclusivities did not begin to emerge until the negotiation of the Agreement on Trade-Related Aspects of Intellectual Property Rights⁷ (“TRIPS Agreement”).⁸

3. See, e.g., MICHELE BOLDRIN & DAVID K. LEVINE, *AGAINST INTELLECTUAL MONOPOLY* (2008) (arguing that copyrights and patents are non-essential to creativity and innovation and detrimental to the common good).

4. See JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 106–09 (2008) (noting the important role of patents in supporting innovation in the pharmaceutical and chemical industries); DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 50 (2009) (“[S]tudies found that patents play a major role in supporting innovation in only a few industries, most notably chemistry and pharmaceuticals.”).

5. See GRAHAM DUTFIELD, *INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: PAST, PRESENT AND FUTURE* 59–60 (2d ed. 2009) (discussing the efforts to protect inventions relating to synthetic dyestuffs and how such efforts have paved the way for later protections for pharmaceuticals).

6. See Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 103 (2016) (“Some use ‘data exclusivity’ to refer to statutory prohibitions on submission of abbreviated applications and ‘market exclusivity’ to refer to statutory prohibitions on approval of abbreviated applications and by extension market entry.”); Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46 FLA. ST. U. L. REV. 641, 674–75 (2019) [hereinafter Yu, *Limits to TRIPS Harmonization*] (noting the distinction between “data exclusivities” and “market exclusivities”); Peter K. Yu, *Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals*, 6 TEX. A&M L. REV. ARGUENDO 22, 27 (2018) [hereinafter Yu, *Data Exclusivities*] (“While [market exclusivity] prevents the marketing of a new drug based on the utilization of or reliance on previously submitted clinical trial data, [data exclusivity] prevents the utilization or reliance of those data during the exclusivity term.”).

7. 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].

8. See CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 351 (2d ed. 2020)

Article 39.3 provides pharmaceutical developers with protections for the undisclosed test or other data they submit to regulatory authorities for the marketing approval of their products.⁹ In the first decade of the World Trade Organization (“WTO”), Article 70.9 further granted exclusive marketing rights to pharmaceutical developers for up to five years in countries that had not yet completed the transition to offer patent protection to pharmaceutical products.¹⁰

Because of their fairly late arrival, regulatory exclusivities have traditionally been added to patents as an alternative or a supplemental form of protection.¹¹ Such addition is understandable

(“[T]he ... international regime on undisclosed information ... is one of the most significant innovations brought about by the TRIPS Agreement.”); U.N. CONF. ON TRADE & DEV.–INT’L CTR. FOR TRADE & SUSTAINABLE DEV. PROJECT ON INTELLECTUAL PROP. RIGHTS & SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 522 (2005) [hereinafter TRIPS RESOURCE BOOK] (“TRIPS is the first international convention specifically imposing obligations on undisclosed information, including test data.”); JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 4 (2001) (noting that the protection of undisclosed information “has never been the subject of any multilateral agreement” until the adoption of the TRIPS Agreement). As recounted in the *Resource Book on TRIPS and Development*, put together by the United Nations Conference on Trade and Development and the International Centre on Trade and Sustainable Development:

Differences in pre-existing comparative law were even greater with regard to test data relating to pharmaceuticals and agrochemicals. Only a few countries had developed rules on the matter before the negotiation of TRIPS. Thus, the USA introduced a regulatory data protection regime for pesticides in 1972, and in 1984 adopted regulatory exclusivity provisions for medicines. The latter provided for five years of exclusivity for new chemical entities, and three years for data filed in support of authorizations based on new clinical research relating to chemical entities which have already been approved for therapeutic use. The [European Union] member states provided exclusivity protection for the data filed in support of marketing authorization for pharmaceuticals since 1987.

TRIPS RESOURCE BOOK, *supra* note 8, at 522.

9. TRIPS Agreement, *supra* note 7, art. 39.3.

10. *Id.* art. 70.9; *see also* U.N. Sec’y-Gen.’s High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, at 17 (Sept. 2016) (“In 1986, when trade negotiations leading to the establishment of the WTO commenced, 50 countries did not provide patent protection on pharmaceutical products.”).

11. *See* Yu, *Limits to TRIPS Harmonization*, *supra* note 6, at 662–64 (discussing the “question concern[ing] whether data exclusivity protections continue even when the relevant pharmaceutical product is no longer protected by a patent, such as when that product is in the public domain or when the previously granted patent has been subsequently invalidated”).

considering the different nature of and justifications for this extra layer of protection.¹² While patents focus on inventions that have met the novelty, non-obviousness, and utility requirements,¹³ regulatory exclusivities target products that do not fit well with, or do not receive adequate protection from, the patent system. An oft-cited example in recent years is biological products, which many policymakers, industry leaders, and commentators have considered insufficiently protected under existing patent law.¹⁴

While it is easy to understand the concerns about inadequate protection for pharmaceutical innovations, and the benefits of advances in medicines and health technologies, the overprotection of intellectual property rights can greatly reduce public access to essential medicines.¹⁵ Indeed, the access-to-medicines debate has remained vibrant and highly contentious since the TRIPS Agreement entered into force more than two decades ago. Particularly notable are problems relating to therapeutic treatments for HIV/AIDS, tuberculosis, and malaria in Sub-Saharan Africa.¹⁶ These problems

12. See Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 357 (2019) (“The patent regime is one-size-fits-all; it protects new, useful, and nonobvious inventions subject to sufficiency of disclosure. In contrast, the data exclusivity regime has both a different target (only pharmaceuticals) and purpose (efficacy and safety).”).

13. See 35 U.S.C. §§ 101–103 (2018) (providing the novelty, non-obviousness, and utility requirements); TRIPS Agreement, *supra* note 7, art. 27.1 (“[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”).

14. See Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419, 450–61 (2012) (discussing why patents may not provide sufficient protection to biological products); W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 527 (2014) (“[T]he public disclosure required by a patent can lower that entry barrier by providing information about both the biologic-specific manufacturing process and general manufacturing processes for biologics, making patents particularly unattractive.”).

15. See Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1567 n.14 (2013) [hereinafter Yu, *Virotech Patents*] (collecting books on the access-to-medicines problems in relation to the TRIPS Agreement).

16. 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

eventually led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health¹⁷ in November 2001 and the introduction of an amendment to the TRIPS Agreement in December 2005.¹⁸ Domestically, the high drug and healthcare costs have also alarmed the sick, the elderly, and the public at large.¹⁹ It is therefore no surprise that political debates have prominently featured healthcare reforms, especially before presidential elections.²⁰

In view of these ongoing tensions and potential conflicts, commentators have actively questioned the wisdom of providing regulatory exclusivities on top of the already very strong protection for patents under existing law.²¹ The recent years have also seen commentators calling on the incentive framework for pharmaceutical innovation to grant drug developers only one form of protection, but not both.²² The potential policy choices—and the need for a deeper

Aginam, John Harrington & Peter K. Yu eds., 2013) (collecting articles that discuss the access-to-medicines problems in relation to HIV/AIDS).

17. Doha Declaration, *supra* note 16.

18. General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8, 2005); *see also* Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 872–86 (2007) (tracing the development of Article 31*bis* of the TRIPS Agreement).

19. *See* Yu, *Virotech Patents*, *supra* note 15, at 831 (“Due to aging populations and increasing reliance on prescription drugs, developed countries ... face increasingly ‘strain[ed] government budgets and burden[ed] private health benefits systems.’” (quoting Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 27, 29 (Pedro Roffe et al. eds., 2006))).

20. *See, e.g.*, Julie Rovner, *U.S. Elections 2020: Understanding What’s at Stake for Health Care*, NPR, Jan. 29, 2020, <https://www.npr.org/sections/health-shots/2020/01/29/800652075/u-s-elections-2020-understanding-whats-at-stake-for-health-care> [<https://perma.cc/P4GJ-Z94L>] (highlighting the key healthcare issues at play in the 2020 U.S. presidential election); *see also* Yu, *Virotech Patents*, *supra* note 15, at 1565 (noting the controversies surrounding Congress’ adoption of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 during the Obama Administration).

21. *See infra* text accompanying notes 23–30.

22. *See* ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES 103 (2019) (calling for the implementation of “a ‘one and done’ principle for the protection of drug innovation”); Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399 (2013) (proposing a non-patent exclusivity system administered by the U.S. Food and Drug Administration to provide incentives in the area of genetic materials); Heled, *Patents vs. Statutory Exclusivities*, *supra* note 14 (questioning the need for and purpose of having both patents and statutory exclusivities in the area of biological products); Yu, *The International Enclosure Movement*, *supra* note 18, at 895 (“If additional incentives

understanding of the different modalities of protection—provided a key driving force behind this Symposium.

For instance, John Thomas, who spoke at the opening panel of this Symposium, explored in an earlier article the implications of the pharmaceutical industry's growing preference for regulatory exclusivities to patent protection.²³ Likewise, Robin Feldman documented the rise of “regulatory property” as a new form of intellectual property.²⁴ In her latest book, *Drugs, Money, and Secret Handshakes*, Professor Feldman called for the implementation of “a ‘one and done’ principle for the protection of drug innovation” that would require pharmaceutical developers to “choose whether its period of exclusivity should be a patent, an orphan drug designation, or a period of data exclusivity for safety and efficacy data, or something else—but not all of the above and more.”²⁵ In the area of genetic materials, Gregory Dolin also proposed a non-patent exclusivity system administered by the U.S. Food and Drug Administration to generate the incentives that the patent system traditionally provides.²⁶ At the international level, Daniel Gervais advanced an innovative proposal that would extend data exclusivities if “no patent is applied for or the patentee lets it lapse ... [and if an abridged version of the] clinical data are made available to the public.”²⁷

Noting the need for more sophisticated analyses of the interplay between patents and regulatory exclusivities, Yaniv Heled, who participated in this Symposium, questioned in prior work the need for and purpose of having both patents and statutory exclusivities in the area of biological products.²⁸ In his view, such concurrent protection will “waste ... societal resources” while “giv[ing] rise to

are provided by the data exclusivity regime, one has to wonder whether patent protection should be weakened proportionally to reflect the additional incentives.”); Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 785 (2010) (“[I]f data exclusivity laws are to be adopted, one has to wonder whether existing patent rights need to be curtailed proportionally to reflect the additional incentives.”).

23. John R. Thomas, *The End of Patent Medicines: Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39 (2015).

24. Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53 (2016).

25. FELDMAN, *supra* note 22, at 103.

26. Dolin, *supra* note 22.

27. Gervais, *supra* note 12, at 364.

28. Heled, *Patents vs. Statutory Exclusivities*, *supra* note 14.

unnecessary and avoidable risks of abuse.”²⁹ To alleviate these shortcomings, policymakers should pay greater attention to the substitutionary effects of patents and regulatory exclusivities.³⁰

In his contribution to this Symposium, Professor Heled built on his earlier research on biological products to evaluate the first decade of the Biologics Price Competition and Innovation Act, which Congress enacted in 2010.³¹ Using original data and advancing a new method for comparing competition in drug markets, this timely article “surveys the state of competition in United States biologics markets, entry of follow-on biologics . . . into these markets, and the effects such entry has had on biologics prices.”³² The article laments the statute’s significant underperformance in comparison with the Hatch–Waxman Act of 1984³³ and its “fail[ure] to achieve its goal of significantly increasing access to biologics in the United States.”³⁴

Taken together, the scholarship in this area has invited us to interrogate more deeply the role of patents and regulatory exclusivities in pharmaceutical innovation and the interplay between these two forms of protection. As the use of personalized medicines and biological products becomes more popular and affordable,³⁵ the debate on the modalities of protection will only receive more scholarly, policy, and regulatory attention. At the international level, this debate will also garner greater interest, due in large part to the

29. *Id.* at 462 (capitalization omitted); see also Srividhya Ragavan, *The Drug Debate: Data Exclusivity Is the New Way to Delay Generics*, 50 CONN. L. REV. CONTEMPLATIONS 1, 4 (2018) (“[T]he data exclusivity regime can operate in parallel with the patent regime to add a layer of protection for the clinical trial data.”).

30. See CORREA, *supra* note 8, at 361 (“Data protection systems could, if they provided exclusivity, become a partial substitute for patent protection.”); Yu, *Limits to TRIPS Harmonization*, *supra* note 6, at 663 (“For pharmaceutical products that patent law no longer protects, . . . data exclusivity law could provide substitutional protection.”).

31. H.R. 3590, 111th Cong. (2010).

32. Yaniv Heled, *The Biologics Price Competition and Innovation Act at 10—A Stocktaking*, 7 TEX. A&M J. PROP. L. 81, 83 (2021) [hereinafter Heled, *BPCIA at 10*].

33. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 156, 98 Stat. 1585, 1598 (codified at 15 U.S.C. § 355 (2018)).

34. Heled, *BPCIA at 10*, *supra* note 32, at 101.

35. See Yu, *Limits to TRIPS Harmonization*, *supra* note 6, at 689 (“The second new technological development, which ‘has . . . revolutionized the healthcare and pharmaceutical industries,’ is the growing importance and popularity of biologics and personalized medicines.” (quoting Yu, *Data Exclusivities*, *supra* note 6, at 22)).

varied developments in different parts of the world and the fact that many countries are only beginning to focus attention on the development of biological products.³⁶

III. CHALLENGES

Another key inspiration for this Symposium emerges from the rapid changes in the domestic and global pharmaceutical landscapes and the ongoing challenges posed by new geopolitical and technological developments. The scope and length of this Article do not allow for an expanded discussion of the myriad challenges that are now emerging in the domestic and international pharmaceutical arenas. This Part focuses instead on three sets of primary challenges: (1) the development of bilateral, regional, and plurilateral trade agreements; (2) the emergence of technological advances in pharmaceutical innovation; and (3) the ongoing and ever-growing rivalry between China and the United States.

A. *Non-multilateral Trade Agreements*

The first set of challenges concerns the development of bilateral, regional, and plurilateral trade agreements.³⁷ Particularly controversial is the aggressive use of these agreements to push for stronger protections for patents and regulatory exclusivities in the past two decades.³⁸ Less than a year before this Symposium, Canada, the United States, and Mexico signed the United States–Mexico–Canada

36. Cf. WORLD HEALTH ORG., CHINA POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 19–21 (2017) [hereinafter WHO CHINA STUDY] (prepared by Frederick Abbott) (discussing the growing development of biological products in China).

37. For discussions of free trade agreements in the intellectual property context, see generally INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS (Christopher Heath & Anselm Kamperman Sanders eds., 2007); 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); Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 392–400 (2004).

38. See Yu, *Limits to TRIPS Harmonization*, *supra* note 6, at 672–85 (discussing the development of bilateral, regional, and plurilateral trade agreements to strengthen protection for undisclosed test or other data for agrochemical, pharmaceutical, and biological products).

Agreement³⁹ (“USMCA”),⁴⁰ which aimed to replace the North American Free Trade Agreement.⁴¹ Article 20.48 of the USMCA provides protection to undisclosed test or other data for pharmaceutical products “for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.”⁴² The provision further enhances the protections for new clinical information or molecular variations through two alternative routes.⁴³ The first route requires signatories to provide protection “for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation, or new method of administration.”⁴⁴ The second route allows signatories to offer protection “for a period of at least five years to new pharmaceutical products that contain a chemical entity that has not been previously approved in that Party.”⁴⁵

With respect to undisclosed test or other data for biological products, Article 20.49 of the now-amended 2018 text provides protection “for a period of at least ten years from the date of first marketing approval of that product.”⁴⁶ This provision states explicitly that the protection will be extended,

at a minimum, [to] a product that is produced using biotechnology processes and that is, or contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic

39. United States–Mexico–Canada Agreement, Can.–Mex.–U.S., Nov. 30, 2018, <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement> [<https://perma.cc/5BPT-SQY2>] [hereinafter USMCA].

40. For a student note on the USMCA from a past member of this *Journal*, see Jordan Jensen, Note, *Biologics Under a New NAFTA: How TPP Fixed NAFTA’s Intellectual Property Provisions but Not its Investment Provisions*, 5 TEX. A&M J. PROP. L. 247 (2019) (providing an assessment of the USMCA intellectual property and investment provisions in the area of biological products).

41. North American Free Trade Agreement, Can.–Mex.–U.S., Dec. 17, 1992, 32 I.L.M. 289 (1993); see also USMCA, *supra* note 39, pmbl. (stipulating the objective of “replac[ing] the 1994 North American Free Trade Agreement with a 21st Century, high standard new agreement to support mutually beneficial trade leading to freer, fairer markets, and to robust economic growth in the region” (capitalization omitted)).

42. USMCA, *supra* note 39, art. 20.48.1(a).

43. *Id.* art. 20.48.2.

44. *Id.* art. 20.48.2(a).

45. *Id.* art. 20.48.2(b).

46. *Id.* art. 20.49.1.

product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition.⁴⁷

Shortly after this Symposium, the USMCA signatories agreed to amend the agreement by removing Article 20.49 and other contentious provisions.⁴⁸ Such removal addressed the concern U.S. policymakers had over the agreement's high protections for biological products and their request for the United States Trade Representative to "amend the USMCA to increase competition and enhance patient access to more affordable prescription drugs," including biological products.⁴⁹ In the wake of this amendment, the current version of the USMCA no longer includes language protecting the undisclosed test or other data for biological products.

Although commentators often criticize bilateral, regional, and plurilateral trade agreements for their deleterious effects on developing countries, it is important to remember that the binding obligations in these agreements constrain the United States the same way they constrain other signatories.⁵⁰ Because the incentive framework needed to promote pharmaceutical innovation tends to vary according to medical needs, market conditions, and technological advances, what works well for today's industry may not be suitable in the future or in the event of a national emergency. A trade agreement that allows for a limited set of policy options could be detrimental to the United States because it could easily lock the country into outdated standards that impede the future development of the local pharmaceutical industry.⁵¹ Such locked-in standards are particularly

47. *Id.* art. 20.49.2 (footnote omitted).

48. Protocol of Amendment to the Agreement Between the United States of America, the United Mexican States, and Canada art. 3.E, Can.–Mex.–U.S., Dec. 10, 2019, <https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Protocol-of-Amendments-to-the-United-States-Mexico-Canada-Agreement.pdf> [<https://perma.cc/X79R-2RRS>].

49. Letter from Representative Jan Schakowsky et al. to Robert E. Lighthizer, U.S. Trade Representative (July 11, 2019), <https://schakowsky.house.gov/sites/schakowsky.house.gov/files/migrated/uploads/lighthizermeds.pdf> [<https://perma.cc/V8JB-88WF>].

50. See Anupam Chander, *Exporting DMCA Lockouts*, 54 CLEV. ST. L. REV. 205, 207 (2006) ("FTA [free trade agreement] obligations, it must be remembered, generally apply equally to the United States. Thus, it is possible that the United States could run afoul of its own FTAs.").

51. See Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA*, 64 SMU L. REV. 975, 1066–70 (2011) (lamenting how the Anti-Counterfeiting Trade

problematic in a fast-growing area like biological products.⁵² Should the United States need to adjust these standards beyond what the existing agreements permit, it will have to withdraw from those agreements, ask its trading partners for support to amend the agreements, or face consequences for noncompliance.⁵³

B. *Technological Advances*

The second set of challenges relates to the emergence of technological advances in pharmaceutical innovation. Part II already acknowledged the ever-increasing popularity of biological products and personalized medicines. There are other emergent developments, however. For example, a fast-growing number of commentators are now exploring the use of artificial intelligence (“AI”) and machine learning in the pharmaceutical sector, including for research and development.⁵⁴ Advances in this area have also attracted the attention

Agreement will foreclose opportunities for future legislative reform).

52. See Trans-Pacific Partnership Agreement art. 18.51.3, Feb. 4, 2016, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> [<https://perma.cc/BU94-JYH6>] (“Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time . . .”).

53. See Chander, *supra* note 50, at 207 (“Should we conclude in the future that the [Digital Millennium Copyright Act] anti-circumvention rules [that have been built into a FTA] are too constricting, we will have to renegotiate the FTA, flout the FTA, or conform to an uncongenial rule.”).

54. See Pratap Khedkar & Dharmendra Sahay, *Trends in Healthcare and Medical Innovation*, in GLOBAL INNOVATION INDEX 2019: CREATING HEALTHY LIVES—THE FUTURE OF MEDICAL INNOVATION 87, 89 (Soumitra Dutta et al. eds., 2019) [hereinafter GLOBAL INNOVATION INDEX 2019] (“A third of all AI investments in healthcare are projected to be in drug discovery, specifically using computer simulation to find better molecules faster. Companies are also beginning to leverage AI and data to reduce clinical trial costs and waste, though progress has been slower than desired.” (footnote omitted)); WORLD HEALTH ORG. ET AL., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 89 (2d ed. 2020) [hereinafter TRILATERAL STUDY] (“Artificial neural networks . . . have been used in drug discovery for screening compounds in the automated design of new classes of medicines and in finding novel uses for known medicines. . . . AI is already being used in the design and analysis of clinical trials.”). For the use of artificial intelligence and machine learning in the health area, see generally Ma Huateng, Tencent, *Application of Artificial Intelligence and Big Data in China’s Healthcare Services*, in GLOBAL INNOVATION INDEX 2019, *supra*, at 103 (2019); ERIC J. TOPOL, DEEP MEDICINE: HOW ARTIFICIAL INTELLIGENCE CAN MAKE HEALTHCARE HUMAN AGAIN (2019); David W. Opperbeck, *Artificial Intelligence in Pharmaceuticals, Biologics, and Medical Devices: Present and Future Regulatory Models*, 88 FORDHAM L. REV. 553 (2019); W. Nicholson Price II,

of those involved in compiling the Global Innovation Index, who selected the future of medical innovation as the theme of their 2019 report.⁵⁵

In addition, big data analytics have already “transformed the fields of biotechnology and bioinformatics while ushering in major advances in drug development, clinical practices, and medical financing.”⁵⁶ With increased data value, pharmaceutical developers understandably will want stronger protection for their undisclosed test or other data. After all, the more protection they secure, the more value they can extract from the data and the more lead time they will have for such extraction.⁵⁷ Moreover, the use of big data analytics in the pharmaceutical sector may require the provision of new incentives to motivate drug developers to upgrade their legacy technologies and to invest in new analytical tools to optimize innovation, improve clinical trial efficiency, and strengthen product quality, safety, and efficacy.⁵⁸

Medical AI and Contextual Bias, 33 HARV. J.L. & TECH. 65 (2019); W. Nicholson Price II & Arti K. Rai, *Clearing Opacity Through Machine Learning*, 106 IOWA L. REV. 775 (2021).

55. GLOBAL INNOVATION INDEX 2019, *supra* note 54.

56. Yu, *Data Exclusivities*, *supra* note 6, at 22; see also Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 227 (2013) (noting that “‘big data’ is altering new drug development, clinical practices, and health care financing”); Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of New Medicines*, 20 YALE J.L. & TECH. 1, 32–34 (2018) (discussing the use of big data and in silico screening of chemical compounds); Jamie Cattell et al., *How Big Data Can Revolutionize Pharmaceutical R&D*, MCKINSEY & CO. (Apr. 2013), <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-big-data-can-revolutionize-pharmaceutical-r-and-d> [<https://perma.cc/X3H5-7STE>] (“In research and development ... big data and analytics are being adopted across industries, including pharmaceuticals.”).

57. Extracting value from these data can be complicated, as a substantial portion of the value derives from the reuse, or initially unintended use, of the data. See Mark Burdon & Mark Andrejevic, *Big Data in the Sensor Society*, in *BIG DATA IS NOT A MONOLITH* 61, 69 (Cassidy R. Sugimoto et al. eds., 2016) (noting that the value in data “is provided by the fact that personal data can be aggregated with that of countless other users (and things) in order to unearth unanticipated but actionable research findings”); VIKTOR MAYER-SCHÖNBERGER & KENNETH CUKIER, *BIG DATA: A REVOLUTION THAT WILL TRANSFORM HOW WE LIVE, WORK AND THINK* 153 (2014) (“[I]n a big-data age, most innovative secondary uses haven’t been imagined when the data is first collected.”); Margaret Foster Riley, *Big Data, HIPAA, and the Common Rule: Time for Big Change?*, in *BIG DATA, HEALTH LAW, AND BIOETHICS* 251, 251 (I. Glenn Cohen et al. eds., 2018) (“The analysis of Big Data related to healthcare is often for a different purpose than the purpose for which the data were originally collected.”).

58. See W. Nicholson Price II, *Big Data, Patents, and the Future of Medicine*,

These costly investments, in turn, will generate a new cycle of demands for stronger data protection to help recoup the developers' up-front investments.⁵⁹ In responding to these demands, policymakers should exercise caution, as overprotection could fragment the data market and thereby undermine the benefits of new, innovative data analytical techniques.⁶⁰

C. U.S.–China Rivalry

The final set of challenges pertains to the ongoing and ever-growing rivalry between China and the United States. Although intellectual property problems in China have been the subject of a

37 CARDOZO L. REV. 1401 (2016) (calling for the building of infrastructure for transformative medical innovation to provide incentives for developing personalized medicine and related diagnostic tests and algorithms); Cattell et al., *supra* note 56 (estimating that the application of big-data strategies “to better inform decision making could generate up to \$100 billion in value annually across the US health-care system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches”); Megan Nichols, *5 Ways Big Data Is Transforming the Pharmaceutical Industry*, GEEKTIME (May 8, 2017), <https://perma.cc/FJF6-SYHN> (“Using Big Data and predictive analysis, companies can conduct effective clinical trials. The patients selected for these trials can meet certain prerequisites found through multiple databases, and researchers can monitor the participants in real-time.”).

59. See Nichols, *supra* note 58 (“Cost is one of the largest factors in the slow growth and acceptance of Big Data analytics in the pharmaceutical industry. It’s expensive to overhaul an entire infrastructure, so many companies are breaking changes down into small compartments in order of priority.”); Yu, *Limits to TRIPS Harmonization*, *supra* note 6, at 687–88 (“With ... costly expenditures [in upgrading technology and investing in new analytical tools], one can only assume that private industries would want stronger protection of their proprietary data to help recoup those up-front investments.”).

60. See Josef Drexl, *Designing Competitive Markets for Industrial Data: Between Propertisation and Access*, 8 J. INTEL. PROP. INFO. TECH. & ELEC. COM. L. 257, 260 & n.16 (2017) (considering “multiple ownership of the same data with considerable negative effects on access to that data” as “a situation of a ‘tragedy of the anti-commons’ in which too many property rights in the same asset lead to inefficient underuse of that asset”); Wolfgang Kerber, *A New (Intellectual) Property Right for Non-Personal Data? An Economic Analysis*, 2016 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT INTERNATIONALER TEIL [GRUR INT] 989, 990 (positing that the introduction of new intellectual property right in data “can be ... dangerous for innovation and competition in the digital economy, because it might lead to considerable legal uncertainty, the monopolisation of information, and impediments for the free flow of data that is so crucial for the digital economy”); Peter K. Yu, *Data Producer’s Right and the Protection of Machine-Generated Data*, 93 TUL. L. REV. 859, 889 (2019) (noting that the fragmentation of the data market could “undermin[e] the benefits of new, innovative data analytical techniques”).

perennial debate,⁶¹ and continue to attract attention from U.S. policymakers,⁶² the fast-escalating trade war between the two countries has generated new tensions and conflicts that we have not seen since the mid-1990s.⁶³ A few months before this Symposium, China and the United States threatened each other with tens or hundreds of billions of dollars in trade tariffs.⁶⁴ As partial relief, these countries signed the so-called “Phase One” agreement in January

61. For the Author’s earlier discussions of the piracy and counterfeiting problems in China, see generally Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 173 (Daniel J. Gervais ed., 1st ed. 2007); Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-first Century*, 50 AM. U. L. REV. 131 (2000) [hereinafter Yu, *From Pirates to Partners I*]; Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in Post-WTO China*, 55 AM. U. L. REV. 901 (2006); Peter K. Yu, *The Middle Kingdom and the Intellectual Property World*, 13 OR. REV. INT’L L. 209 (2011).

62. See OFFICE OF THE U.S. TRADE REPRESENTATIVE, FINDINGS OF THE INVESTIGATION INTO CHINA’S ACTS, POLICIES, AND PRACTICES RELATED TO TECHNOLOGY TRANSFER, INTELLECTUAL PROPERTY, AND INNOVATION UNDER SECTION 301 OF THE TRADE ACT OF 1974 (2018) (providing the final report of the Section 301 investigation on Chinese laws, policies, and practices in the areas of intellectual property, innovation, and technology development); OFFICE OF THE U.S. TRADE REPRESENTATIVE, UPDATE CONCERNING CHINA’S ACTS, POLICIES AND PRACTICES RELATED TO TECHNOLOGY TRANSFER, INTELLECTUAL PROPERTY, AND INNOVATION (2018) (providing an update to the earlier report); Request for Consultations by the United States, *China—Certain Measures Concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS542/1 (Mar. 23, 2018) (providing the United States’ second WTO complaint against China that focused primarily on the violation of the TRIPS Agreement).

63. See Yu, *From Pirates to Partners I*, *supra* note 61, at 154, 170 (discussing the high U.S.–China tensions in the mid-1990s when the United States dispatched an aircraft carrier group to the Taiwan Strait following a large-scale Chinese naval exercise and when the United States mistakenly bombed the Chinese embassy in Belgrade, Serbia).

64. See, e.g., *Trump: U.S. Will Hit \$300 Billion Worth of Chinese Goods with 10% Tariff*, REUTERS (Aug. 1, 2019), <https://www.reuters.com/article/us-usa-trade-china-tariffs/trump-says-u-s-to-hit-300-billion-worth-of-chinese-goods-with-10-tariff-idUSKCN1UR5CK> [<https://perma.cc/S4DW-DDZG>] (announcing the imposition of an additional 10% tariff on \$300 billion worth of Chinese imports); Se Young Lee & Judy Hua, *China Strikes Back at U.S. with New Tariffs on \$75 Billion in Goods*, REUTERS (Aug. 23, 2019), <https://www.reuters.com/article/us-usa-trade-china/china-strikes-back-at-us-with-new-tariffs-on-75-billion-in-goods-idUSKCN1VD1AJ> [<https://perma.cc/KK6H-9FN6>] (announcing the imposition of an additional 10% retaliatory tariffs on \$75 billion worth of U.S. imports); see also 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/3GN3-CEJA>] (providing an updated timeline of these tariffs).

2020.⁶⁵ At the signing of the agreement, some trade experts already noted the unrealistic nature of some commitment targets.⁶⁶ With the changing circumstances precipitated by the COVID-19 pandemic, it has become even more unlikely that the agreement will be fully implemented.⁶⁷

As far as pharmaceutical innovation is concerned, the rivalry between China and the United States is important for three reasons. First, China is, at present, the world's leading supplier of active pharmaceutical ingredients ("APIs").⁶⁸ It also has the world's second largest pharmaceutical market⁶⁹ while producing about four percent of

65. Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, China–U.S., Jan. 15, 2020, <https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china/phase-one-trade-agreement/text> [<https://perma.cc/LP3S-M3AB>].

66. See Jason Bordoff, *Trump's China Trade Deal Is as Dead as Can Be His Much-Touted Trade Victory Has Crashed and Burned with the Coronavirus Pandemic*, FOREIGN POL'Y (May 22, 2020), <https://foreignpolicy.com/2020/05/22/trump-trade-deal-china-dead-coronavirus-pandemic/> [<https://perma.cc/G7TV-LB3C>] ("The targets [for the Phase One U.S.–China trade deal] were unrealistic even before the ink was dry in January."); David Lawder & Andrea Shalal, *China to Ramp up U.S. Buys Under Trade Deal, but Skeptics Question Targets*, REUTERS (Jan. 13, 2020), <https://www.reuters.com/article/us-usa-trade-china/china-to-ramp-up-u-s-buys-under-trade-deal-but-skeptics-question-targets-idUSKBN1ZD0FN> [<https://perma.cc/5DHE-TK63>] ("[S]ome U.S. trade experts call [China's pledge to buy almost \$80 billion of additional manufactured goods from the United States over the next two years] an unrealistic target").

67. See Bordoff, *supra* note 66 ("Amid the collapse in oil demand and prices unleashed by the pandemic, it is now all but certain that China will fail to meet its targets for energy purchases."); Yen Nee Lee, *China's Purchases of US Goods Will Fall Way Short of "Phase One" Trade Deal Due to the Coronavirus, Says Think Tank*, CNBC (May 11, 2020), <https://www.cnbc.com/2020/05/11/coronavirus-us-exports-to-china-to-fall-short-of-phase-one-trade-deal-says-csis.html> [<https://perma.cc/SQ3K-AELE>] (reporting the forecast of the Center for Strategic and International Studies that "[t]he coronavirus pandemic will cause China's purchases of U.S. goods [in 2020] to fall way short of what was agreed to in the 'phase one' trade deal").

68. See 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."); see also WHO CHINA STUDY, *supra* note 36, at 17 ("China is the world's leading producer and exporter of [APIs] by volume, accounting for 20% of total global API output. China produces over 2000 API drug products, with annual production capacity exceeding 2 million tons." (footnote omitted)).

69. See Issaku Harada, *China Extends Drug Patents to 25 Years*, NIKKEI ASIAN REV. (May 16, 2018), <https://asia.nikkei.com/Politics/China-extends-drug-patents->

the world's new pharmaceutical products.⁷⁰ Indeed, the country's fast-expanding role in the global pharmaceutical landscape has sparked major concerns among U.S. policymakers and the American public. In *China Rx*, Rosemary Gibson and Janardan Prasad Singh warned 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.⁷¹ In the past few months, those worrying about the potential shortages of medicines amid the COVID-19 pandemic also lamented the country's continuous and increasing dependence on Chinese pharmaceutical products and ingredients.⁷² It is therefore no surprise that the U.S. administration—and, for that matter, other governments—has now actively pushed for nationalist policies to address the global pandemic. The next Part will discuss this problematic approach in greater detail.⁷³

Second, since the mid-2000s, China's intellectual property laws and policies in the pharmaceutical sector have undergone radical

to-25-years [<https://perma.cc/QS2S-5Q8F>] (“China’s pharmaceutical market is now worth more than \$120 billion, second only to America’s.”).

70. See CHINA PHARM. ENTERS. ASS’N ET AL., FOSTERING A SUSTAINABLE ECOSYSTEM FOR DRUG INNOVATION IN CHINA 3 (2016), http://enadmin.rdpac.org/upload/upload_file/1577873373.pdf

[<https://perma.cc/UE2Q-ZT4K>] (“Measured by the number of pipeline drugs and new drugs launched, China is in the third tier, contributing around 4% to global drug innovations, lagging far behind the first tier[,] the US (~50%)[,] and countries in the second tier such as the UK and Japan.”); Ma, *supra* note 54, at 108 (“China has independently researched and developed new drugs in recent years that have contributed about 4% to the global novel drug market, approximately one-twelfth of the contribution from that of the United States of America.”).

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

72. See Ana Swanson, *Coronavirus Spurs U.S. Efforts to End China’s Chokehold on Drugs*, N.Y. TIMES (Mar. 11, 2020), <https://www.nytimes.com/2020/03/11/business/economy/coronavirus-china-trump-drugs.html> [<https://perma.cc/A8BG-EHTC>] (“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/FWS5-5Z2R>] (“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.”).

73. See discussion *infra* Part IV.

transformations. Although the country declined to offer patent protection to pharmaceutical products when it adopted the first modern patent law in 1984 and has remained reluctant to strengthen protections in the two ensuing decades,⁷⁴ China took an “innovative turn” in the mid-2010s, shortly after its State Council adopted the National Intellectual Property Strategy.⁷⁵ By now, it is quite clear that China is no longer content with being the world’s leading API supplier but also “wants to develop a research-based pharmaceutical industry.”⁷⁶

A case in point is the draft Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products, which the National Medical Products Administration of China released in April 2018.⁷⁷ The proposed Article 5 not only provides six years of protection to data submitted for the regulatory approval of innovative drugs (*chuangxin yao*)⁷⁸—a TRIPS-plus standard that China accepted upon WTO accession⁷⁹—but the provision also offers twelve years of protection to undisclosed test or other data for

74. See Peter K. Yu, *China’s Innovative Turn and the Changing Pharmaceutical Landscape*, 51 U. PAC. L. REV. 593, 596–98 (2020) [hereinafter Yu, *China’s Innovative Turn*] (discussing China’s reluctance to strengthen patent protection for pharmaceutical products in the 1980s and 1990s).

75. See *id.* at 594 (“Since the mid-2000s, China has taken an innovative turn that has serious ramifications for the global pharmaceutical landscape and future developments at the intersection of intellectual property and public health.”); see also Peter K. Yu, *A Half-Century of Scholarship on the Chinese Intellectual Property System*, 67 AM. U. L. REV. 1045, 1079–87 (2018) [hereinafter Yu, *A Half-Century of Scholarship*] (discussing the State Council’s adoption of the National Intellectual Property Strategy and China’s innovative turn).

76. Yu, *Limits to TRIPS Harmonization*, *supra* note 6, at 693–94.

77. Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products, <https://chinaipr2.files.wordpress.com/2018/04/draftdata-exclusivityrules.doc> [<https://perma.cc/3YFE-SURG>] (China) (in Chinese) [hereinafter Provisional Measures]; see also Mark Cohen, *Draft of Data Exclusivity Rules Released by CFDA*, CHINA IPR (Apr. 26, 2018), <https://chinaipr.com/2018/04/26/draft-of-data-exclusivity-rules-released-by-cfda/> [<https://perma.cc/963J-6U5E>] (outlining the changes brought about by these provisional measures). The National Medical Products Administration of China is the successor to the Food and Drug Administration of China.

78. Provisional Measures, *supra* note 77, art. 5.

79. See World Trade Org., *Report of the Working Party on the Accession of China* ¶ 284, WTO Doc. WT/ACC/CHN/49 (Oct. 1, 2001) (committing to the “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”).

innovative therapeutic biologics (*chuangxin zhiliao yong shengwu zhipin*).⁸⁰ This twelve-year standard will put China in parity with the United States.⁸¹ It will also be “higher than the standard laid down in even the most aggressive TRIPS-plus bilateral, regional, and plurilateral agreements.”⁸²

Finally, the recent years have seen China playing important roles in pushing for the greater use and development of artificial intelligence and machine learning in the health arena.⁸³ 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.⁸⁴

In terms of health patent publications, the *Global Innovation Index 2019* placed China among the top three in the world in biotechnology, pharmaceuticals, and medical technology based on publications from 2010 to 2017.⁸⁵ From 1985 to 2017, “China ranked fourth in the total

80. Provisional Measures, *supra* note 77, art. 5.

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

82. Yu, *China’s Innovative Turn*, *supra* note 74, at 607.

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

84. Ma, *supra* note 54, at 103 (footnote omitted); see also Yu, *Data Exclusivities*, *supra* note 6, at 22 (“The introduction of big data analytics has transformed the fields of biotechnology and bioinformatics while ushering in major advances in drug development, clinical practices, and medical financing.”).

85. Soumitra Dutta et al., *The Global Innovation Index 2019*, in *GLOBAL INNOVATION INDEX 2019*, *supra* note 54, at 1, 48.

number of healthcare AI patent applications filed, contributing to 12% of the total.”⁸⁶ In 2016, China already “surpassed Japan and the European Union to become the world’s second largest healthcare AI applicant ..., which reflects the strong momentum of medical technology innovation in China.”⁸⁷

IV. POSSIBILITIES

After discussing the motivations behind this Symposium, this Part turns to a key goal of the event and this special issue. In addition to taking stock of the legal developments concerning pharmaceutical innovation, which Parts II and III have examined, the Symposium’s organizing team also wants to explore new issues and models that are now emerging at the frontier of the debate at the intersection of intellectual property and public health. For this exploration, we are fortunate to have two highly interesting articles: one on biopharmaceutical standards and the other on vaccine development.

In his article, Jorge Contreras examined the issue of patent disclosure in the standard-setting context,⁸⁸ which is underexplored in the intellectual property literature. Using the case of *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*,⁸⁹ this article draws valuable lessons from the “global standards wars” and the more than three decades of litigation in the information and communication technology sector.⁹⁰ The article shows that “issues surrounding the acquisition and disclosure of patents claiming standardized technologies have more salience in the biopharma sector than commonly believed.”⁹¹ It further calls on “standards organizations operating in the biopharma sector [to] ensure that their

86. Ma, *supra* note 54, at 104.

87. *Id.*

88. Jorge L. Contreras, *Is Biopharma Ready for the Standards Wars?*, 7 TEX. A&M J. PROP. L. 43, 45 (2021) [hereinafter Contreras, *Standards Wars*].

89. *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 457 F. App’x 929 (Fed. Cir. 2011); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 298 F. Supp. 3d 258 (D. Mass. 2018); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 882 F. Supp. 2d 184 (D. Mass. 2011).

90. Jorge L. Contreras, *The Global Standards Wars: Patent and Competition Disputes in North America, Europe and Asia* (Univ. of Utah, S.J. Quinney Coll. of L. Legal Stud. Rsch. Paper Series, Paper No. 353, 2018), <https://ssrn.com/abstract=3106090> [<https://perma.cc/4RZB-VV5Q>].

91. Contreras, *Standards Wars*, *supra* note 88, at 79.

policies and procedures are robust enough to delineate clearly the obligations of participants with respect to patents covering standardized technologies.”⁹²

The second article⁹³ comes from Ana Santos Rutschman, who has written actively in the area of vaccine development long before the COVID-19 pandemic, covering issues relating to the Ebola, Zika, and other viral outbreaks.⁹⁴ Her contribution to this Symposium identifies vaccines in two different types of markets—what she calls “happy markets” and “unhappy markets.”⁹⁵ Given the different market conditions for vaccine development, she invites us to explore whether the rights arising out of vaccine patents can be better interpreted or enforced through a non-property-centric lens.⁹⁶ The article specifically calls for the creation of “a liability regime for critical components of vaccine technology” to help “remove some of the most salient transactional obstacles to the development and commercialization of new and better vaccines.”⁹⁷

While these two contributions help us explore emergent issues and models at the frontier of the pharmaceutical innovation debate, the remainder of this Part will be devoted to a recent event that the Symposium organizers and participants did not anticipate: the COVID-19 pandemic.⁹⁸ Issues sparked by this pandemic are not only timely but also relevant and important to this Symposium, for three

92. *Id.*

93. Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 7 TEX. A&M J. PROP. L. 110 (2021) [hereinafter Rutschman, *Vaccine Markets*].

94. See GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA (Sam F. Halabi et al. eds., 2017) [hereinafter GLOBAL MANAGEMENT OF INFECTIOUS DISEASE] (discussing the Ebola outbreak and its aftermath); Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1218–43 (2018) (discussing the Ebola and Zika outbreaks); Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 734–50 (2019) (tracing the historical development of the race to develop new vaccines); Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L.J.F. 651 (2018) (discussing the Zika outbreak).

95. Rutschman, *Vaccine Markets*, *supra* note 93, at 113–18.

96. See *id.* at 130–31.

97. *Id.* at 111.

98. For discussions of legal issues in relation to the COVID-19 pandemic, see generally ASSESSING LEGAL RESPONSES TO COVID-19 (Scott Burris et al. eds., 2020); Symposium, *Taming COVID-19 by Regulation*, 11 EUR. J. RISK REG. 187 (2020); Symposium, *The International Legal Order and the Global Pandemic*, 114 AM. J. INT’L L. 571 (2020).

reasons. First, they push us to think deeper about the role of patents, regulatory exclusivities, and other incentive frameworks in promoting pharmaceutical innovation. As the proverb goes, necessity is the mother of invention. COVID-19 has presented an unprecedented opportunity to explore the possibilities both within and outside the intellectual property system.⁹⁹ Second, the issues are relevant to the debate in this Symposium because they make salient the nexus between the domestic and international debates and between theory and practice in the area of pharmaceutical innovation. As we have seen firsthand from the ongoing development surrounding the COVID-19 vaccines and treatments, this nexus deserves urgent scholarly and policy attention. Finally, issues relating to the pandemic have involved quite a number of participants to this Symposium. In a way, they provide vivid examples of intellectual property scholarship in action.

Although the origin of SARS-CoV-2—the coronavirus that causes the COVID-19 disease¹⁰⁰—remains a mystery, there is a general consensus that the first viral outbreak occurred in Wuhan, China, at the end of 2019.¹⁰¹ Since then, the virus spread to Europe, the United States, and other parts of the world in multiple directions.¹⁰² In late January 2020, the World Health Organization (“WHO”)

99. See ANDREW T. PRICE-SMITH, *CONTAGION AND CHAOS: DISEASE, ECOLOGY, AND NATIONAL SECURITY IN THE ERA OF GLOBALIZATION* 211 (2009) (“Contagion often proves disruptive to societies, and it is extremely problematic for governance, but it may result in the production of ingenuity that allows societies, economies, and structures of governance to switch to new modes of operation.”); E. Richard Gold, *The Coronavirus Pandemic Has Shattered the Status Quo on Drug Development. We Should Build on That*, FORTUNE (Mar. 26, 2020, 6:30 AM), <https://fortune.com/2020/03/26/coronavirus-vaccine-drug-development-open-science-covid-19-treatment/> [https://perma.cc/66DN-34Q6] (“The COVID-19 pandemic shattered th[e] status quo [on drug development].”).

100. The full name of SARS-CoV-2 is “severe acute respiratory syndrome coronavirus 2.” *Naming the Coronavirus Disease (COVID-19) and the Virus That Causes It*, WORLD HEALTH ORG., [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it) [https://perma.cc/JRC7-8XE7] (last visited Oct. 7, 2020).

101. Press Release, World Health Org., *Pneumonia of Unknown Cause—China Disease Outbreak News* (Jan. 5, 2020), <https://www.who.int/csr/don/05-january-2020-pneumonia-of-unknown-cause-china/en/> [https://perma.cc/9CBA-N3PB].

102. See *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/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020> [https://perma.cc/4R5N-KG3B] [hereinafter *WHO Director-General’s Opening Remarks*] (“There are now more than 118,000 cases in 114 countries, and 4,291 people have lost their lives.”).

declared COVID-19 “a public health emergency of international concern.”¹⁰³ Two months later, on March 11, the international health body classified it as a global pandemic.¹⁰⁴ To prevent the community spread of the coronavirus, national and sub-national governments throughout the world began imposing stay-home or safer-at-home orders, physical distancing recommendations, travel restrictions, and other public health measures.¹⁰⁵

In response to this global pandemic, international intergovernmental bodies quickly mobilized to coordinate efforts to promote access to vaccines, diagnostic kits, therapeutic treatments, medical devices, and other health technologies. For instance, WHO Director General Tedros Ghebreyesus asked “all countries, companies and research institutions to support open data, open science and open collaboration so that all people can enjoy the benefits of science and research.”¹⁰⁶ Likewise, Francis Gurry, the Director General of the

103. *WHO Director-General’s Statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORG. (Jan. 30, 2020), [https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov)) [<https://perma.cc/M9P4-T8A2>].

104. *See WHO Director-General’s Opening Remarks*, *supra* note 102 (“We have ... made the assessment that COVID-19 can be characterized as a pandemic.”); *see also* Jamie Ducharme, *World Health Organization Declares COVID-19 a “Pandemic.” Here’s What That Means*, TIME (Mar. 11, 2020, 12:39 PM), <https://time.com/5791661/who-coronavirus-pandemic-declaration/> [<https://perma.cc/E2XW-CPV8>]. (reporting WHO’s pandemic declaration).

105. *See* TRILATERAL STUDY, *supra* note 54, at 17 (“Governments around the globe have implemented restrictions to economic and social activities in an effort to slow the virus’s spread, including through policies of confinement, physical distancing and restrictions on travel.”). As researchers from the Center for Public Health Law Research at Temple University Beasley School of Law recounted in relation to the United States:

On March 19, 2020, California started a trend of statewide stay-at-home orders. Within the subsequent two weeks, 32 more states and the District of Columbia issued statewide stay-at-home orders ... [T]he remaining six states implemented stay-at-home orders by April 7, 2020, while Arkansas, Connecticut, Iowa, Kentucky, Massachusetts, Nebraska, North Dakota, Oklahoma, South Dakota, Texas, Utah, and Wyoming never issued explicit statewide stay-at-home orders as of July 1, 2020.

Lindsay K. Cloud et al., *A Chronological Overview of the Federal, State, and Local Response to COVID-19*, in *ASSESSING LEGAL RESPONSES TO COVID-19*, *supra* note 98, at 10, 12.

106. *WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19—6 April 2020*, WORLD HEALTH ORG. (Apr. 6, 2020), <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---6-april-2020> [<https://perma.cc/C87Q-A7YJ>].

World Intellectual Property Organization, issued a public statement noting that “emergencies and catastrophes may call for measures that may disrupt the normal functioning of the incentive framework upon which the [intellectual property] system is based.”¹⁰⁷ In addition, the United Nations General Assembly issued a resolution

[e]ncourag[ing] Member States to work in partnership with all relevant stakeholders to increase research and development funding for vaccines and medicines, leverage digital technologies, and strengthen scientific international cooperation necessary to combat COVID-19 and to bolster coordination ... towards rapid development, manufacturing and distribution of diagnostics, antiviral medicines, personal protective equipment and vaccines.¹⁰⁸

The WHO also worked closely with France, other members of the European Union, and the Bill and Melinda Gates Foundation to launch the Access to COVID-19 Tools Accelerator, which “brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations ... to support[] the development and equitable distribution of the tests, treatments and vaccines the world needs to reduce mortality and severe disease.”¹⁰⁹

At the national level, countries quickly adopted new legislation, resolutions, or government decrees to increase the use of flexibilities provided by the TRIPS Agreement, such as the issuance of compulsory licenses under Article 31¹¹⁰ and the utilization of the national security exception under Article 73.¹¹¹ In March 2020, Israel

107. Francis Gurry, *Some Considerations on Intellectual Property, Innovation, Access and COVID-19*, ¶ 5, WORLD INTELL. PROP. ORG. (Apr. 24, 2020), https://www.wipo.int/about-wipo/en/dg_gurry/news/2020/news_0025.html [<https://perma.cc/92K2-ZRHA>].

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

109. *The Access to COVID-19 Tools (ACT) Accelerator*, WORLD HEALTH ORG., <https://www.who.int/initiatives/act-accelerator> [<https://perma.cc/PM4H-VBP4>] (last visited Aug. 23, 2020).

110. See TRIPS Agreement, *supra* note 7, art. 31 (delineating the complex conditions for the use of patents without the right holder’s authorization).

111. See *id.* art. 73(b) (“Nothing in this Agreement shall be construed ... to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests ... in time of ... emergency in international relations”); see also Letter from Carlos Correa, Executive Dir., S.

became the first country to introduce a compulsory license during the global pandemic.¹¹² A few months later, the European Parliament adopted a nonbinding resolution “[c]alling on the [European] Commission and the [European Union] Member States to formally support the COVID-19 Technology Access Pool (C-TAP), allowing maximum sharing of COVID-19 health technology-related knowledge, intellectual property and data to the benefit of all countries and citizens.”¹¹³ Meanwhile, government agencies, private businesses, and not-for-profit organizations launched proactive initiatives to facilitate domestic and international cooperation, ranging from the issuance of open licenses¹¹⁴ to the release of COVID-19 Open Research Dataset¹¹⁵ to public pledges of patented technologies and other intellectual properties.¹¹⁶

In academic and policy circles, commentators advanced innovative proposals to help governments and intergovernmental

Ctr., to Tedros Adhanom Ghebreyesus, Dir.-Gen. of the World Health Org., Francis Gurry, Dir.-Gen. of the World Intellectual Property Org., and Roberto Azevêdo, Dir.-Gen. of the World Trade Org. (Apr. 4, 2020) (“The use of [Article 73] will be fully justified to procure medical products and devices or to use the technologies to manufacture them as necessary to address the current health emergency.”); Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* (S. Ctr., Rsch. Paper No. 116, 2020) (discussing the use of Article 73 in the COVID-19 context).

112. See Adam Houldsworth, *The Key Covid-19 Compulsory Licensing Developments So Far*, IAM (Apr. 7, 2020), <https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far> [<https://perma.cc/S2L8-PVLJ>] (“The only country in which a Covid-19-related compulsory licence has been granted so far is Israel.”). This license sought to import a generic version of AbbVie’s Kaletra (lopinavir/ritonavir) from India for treating COVID-19 patients. *Id.*

113. European Parliament Resolution on the EU’s Public Health Strategy Post-COVID-19, art. 6, 2020/2691(RSP) (July 10, 2020).

114. See *Publishers Make Coronavirus (COVID-19) Content Freely Available and Reusable*, WELLCOME (Mar. 16, 2020), <https://wellcome.ac.uk/press-release/publishers-make-coronavirus-covid-19-content-freely-available-and-reusable> (stating that leading publishers made coronavirus-related works freely available).

115. See Press Release, White House Off. of Sci. & Tech. Pol’y, Call to Action to the Tech Community on New Machine Readable COVID-19 Dataset (Mar. 16, 2020), <https://www.whitehouse.gov/briefings-statements/call-action-tech-community-new-machine-readable-covid-19-dataset/> [<https://perma.cc/GW8S-Q8WJ>] (announcing the joint effort of the White House Office of Science and Technology Policy, the Allen Institute for AI, the Chan Zuckerberg Initiative, Georgetown University, Microsoft, and the National Institutes of Health to release the COVID-19 Open Research Dataset).

116. See discussion *infra* text accompanying notes 150–154 (discussing the Open COVID pledge).

bodies to reduce the barriers that the intellectual property system may pose to efforts addressing the global pandemic. For example, Frederick Abbott and Jerome Reichman proposed legal measures on both the supply and demand sides to promote the “equitable access to vaccines, treatments, diagnostics and medical equipment.”¹¹⁷ Teresa Hackett underscored the important roles played by text and data mining and the right to research during the global pandemic.¹¹⁸ Yaniv Heled, Ana Santos Rutschman, and Liza Vertinsky called for intellectual property law to incorporate the tort law privileges of self-defense and necessity.¹¹⁹ Joshua Sarnoff advocated the development of a more robust legal right to repair and produce the needed medical equipment, spare parts, and products in emergencies.¹²⁰

While most of these developments have been promising and have greatly enhanced domestic and international cooperation, some countries took a different route and opted instead for nationalist pandemic responses. Their choices have raised concerns throughout the world, especially among developing countries. For instance, the Trump Administration has been widely criticized for banning the export of personal protective equipment to other countries, including those that were struggling with similar public health crises.¹²¹ The

117. 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 (2020).

118. Teresa Hackett, *COVID and Copyright: The Right to Research*, ELEC. INFO. FOR LIBR. (Aug. 10, 2020), <https://www.eifl.net/blogs/covid-and-copyright-right-research> [<https://perma.cc/C48A-BP9V>].

119. Yaniv Heled et al., *The Need for the Tort Law Privileges of Self-Defense and Necessity in Intellectual Property Law* (July 3, 2020), <https://ssrn.com/abstract=3642833> [<https://perma.cc/K7WA-J984>].

120. Joshua D. Sarnoff, *TRIPS, COVID-19, and the Right to Repair and Produce Needed Medical Products in Emergencies (Part 1 of 2)*, TRADERX REPORT (June 11, 2020), <https://www.traderxreport.com/covid-19/trips-covid-19-and-the-right-to-repair-and-produce-needed-medical-products-in-emergencies-part-1-of-2/> [<https://perma.cc/M9M8-TLQ6>]; Joshua D. Sarnoff, *TRIPS, COVID-19 and the Right to Repair and Produce Needed Medical Products in Emergencies (Part 2 of 2)*, TRADERX REPORT, (June 11, 2020), <https://www.traderxreport.com/covid-19/trips-covid-19-and-the-right-to-repair-and-produce-needed-medical-products-in-emergencies-part-2-of-2/> [<https://perma.cc/J36E-UCND>].

121. See 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/53W5-H3JN>] (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”).

administration also has embraced a “go it alone” approach to developing COVID-19 vaccines and treatments.¹²² Not only did President Trump refuse to join other world leaders “in a virtual summit ... to pledge billions of dollars to quickly develop vaccines and drugs to fight the coronavirus,”¹²³ but the United States also declined to participate in the COVAX Initiative, which aims to provide fair and equitable access to COVID-19 vaccines throughout the world and which will be further discussed below.¹²⁴

Although the Trump administration’s highly controversial instruction of 3M and other companies not to export personal protective equipment has received wide media coverage,¹²⁵ the United States is not the only country that has taken a nationalist stand during the global pandemic. According to the Global Trade Alert project at

122. As a Congressional Research Service report declared:

In May 2020, the Trump Administration announced the creation of a program called Operation Warp Speed, which seeks to use coordinated government support to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and other medical countermeasures. With respect to vaccines, the program initially selected fourteen promising candidates, which are being narrowed down to “about seven.” Under Operation Warp Speed, the federal government is investing in scaling up manufacturing and distribution for selected COVID-19 vaccine candidates “at risk” (that is, before safety and efficacy is demonstrated). Under the program, [the Biomedical Advanced Research and Development Authority] has entered into agreements to accelerate the development and manufacturing—and to purchase hundreds of millions of doses—for vaccine candidates being developed by AstraZeneca and the University of Oxford, Sanofi and GlaxoSmithKline (GSK), Pfizer and BioNTech, Moderna and NIAID, Novavax, and Johnson & Johnson. By November 2020, three of the manufacturers participating in Operation Warp Speed—Pfizer/BioNTech, Moderna/NIAID, and AstraZeneca/University of Oxford—announced encouraging safety and efficacy results from the Phase 3 trials of their vaccines.

KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46399, LEGAL ISSUES IN COVID-19 VACCINE DEVELOPMENT 1, 1–2 (2020) (footnotes omitted).

123. William Booth et al., *U.S. Skips Virtual Vaccine Summit as World Leaders Pledge Billions to Efforts*, WASH. POST, May 5, 2020, at A1.

124. See discussion *infra* text accompanying notes 155–163 (discussing the COVAX Initiative).

125. See Anya van Wagtenonk, *A White House Order to Keep Masks in the US Could Limit Supply, Companies Warn*, VOX (Apr. 4, 2020), <https://www.vox.com/policy-and-politics/2020/4/4/21208142/coronavirus-ppe-exports-masks-dpa-trump-administration-3m> [https://perma.cc/G3D8-DM9P] (warning that the Trump administration’s policy limiting personal protective equipment exports could backfire on the administration).

the University of St. Gallen in Switzerland, “[a]t least 69 countries have banned or restricted the export of protective equipment, medical devices or medicines.”¹²⁶

As society continues to move forward with the development and procurement of COVID-19 vaccines, policymakers and commentators have become particularly worried about what they have called “vaccine nationalism”¹²⁷ or “pharmaceutical sovereignty.”¹²⁸ From a public health standpoint, the adoption of nationalist policy responses to address the global pandemic, while unsurprising, can be highly dangerous because it will prevent the much-needed international cooperation in the ongoing search for vaccines, treatments, and cures as well as the continuous effort to “contain, mitigate and defeat the pandemic.”¹²⁹ As Kathryn White and Maria

126. Peter S. Goodman et al., *A New Front for Nationalism: The Global Battle Against a Virus*, N.Y. TIMES (Apr. 13, 2020), <https://www.nytimes.com/2020/04/10/business/coronavirus-vaccine-nationalism.html> [<https://perma.cc/6ZY6-BSQJ>].

127. See, e.g., Thomas J. Bollyky & Chad P. Bown, *The Tragedy of Vaccine Nationalism Only Cooperation Can End the Pandemic*, FOREIGN AFFS. (Sept./Oct. 2020), <https://www.foreignaffairs.com/articles/united-states/2020-07-27/vaccine-nationalism-pandemic> [<https://perma.cc/F826-YC8K>]; Ian Bremmer, *What Vaccine Nationalism Means for the Coronavirus*, TIME (July 27, 2020), <https://time.com/5871532/vaccine-nationalism-coronavirus-pandemic/> [<https://perma.cc/7ELZ-D5PL>]; Kate Kelland & Julie Steenhuisen, “Vaccine Nationalism”: Is It Every Country For Itself?, REUTERS (July 29, 2020), <https://www.reuters.com/article/us-health-coronavirus-vaccines-access-an/vaccine-nationalism-is-it-every-country-for-itself-idUSKCN24U2DE> [<https://perma.cc/T78W-TXKZ>]; Kai Kupferschmidt, “Vaccine Nationalism” Threatens Global Plan to Distribute COVID-19 Shots Fairly, SCI. (July 28, 2020), <https://www.sciencemag.org/news/2020/07/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly> [<https://perma.cc/38G5-NRE7>]; Richard Milne & David Crow, *Why Vaccine “Nationalism” Could Slow Coronavirus Fight*, FIN. TIMES (May 13 2020), <https://www.ft.com/content/6d542894-6483-446c-87b0-96c65e89bb2c> [<https://perma.cc/U4X9-EAVB>]; Rebecca Weintraub et al., *The Danger of Vaccine Nationalism*, HARV. BUS. REV. (May 22, 2020), <https://hbr.org/2020/05/the-danger-of-vaccine-nationalism> [<https://perma.cc/ZN5R-JQ79>].

128. Germán Velásquez, *Re-thinking Global and Local Manufacturing of Medical Products After COVID-19*, at 3 (S. Ctr., Rsch. Paper No. 118, 2020).

129. See Global Solidarity to Fight the Coronavirus Disease 2019 (COVID-19), ¶ 5, G.A. Res. 74/270, U.N. Doc. A/RES/74/270 (Apr. 2, 2020) (calling for “intensified international cooperation to contain, mitigate and defeat the pandemic, including by exchanging information, scientific knowledge and best practices and by applying the relevant guidelines recommended by the World Health Organization”).

Banda observed in relation to the outbreak of the H1N1 influenza,¹³⁰ an earlier WHO-declared pandemic:

National pandemic preparedness, by its nature, is an international issue: in a world lacking equitable access to the cure, even the vaccinated would face devastation if the global economy were to stop in its tracks. 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.¹³¹

Because many countries that are breeding grounds for viral outbreaks also struggle with poverty and infrastructure problems,¹³² they need as much international assistance as they can secure. The United States and other developed and emerging countries should therefore provide assistance while actively engaging in greater international cooperation. These countries should do so not only out of altruism but also because of the domestic need to protect national health security.¹³³

130. See generally SARA ELLEN DAVIES ET AL., *DISEASE DIPLOMACY: INTERNATIONAL NORMS AND GLOBAL HEALTH SECURITY* 74–92 (2015) (discussing the H1N1 pandemic).

131. 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); see also 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)).

132. See Anthony S. Fauci, *The Ebola Epidemic of 2014–2015: A Perfect Storm*, in *GLOBAL MANAGEMENT OF INFECTIOUS DISEASE*, *supra* note 94, at 21, 25 (“The Ebola outbreak of 2014–2015 originated in severely under-resourced countries with limited public health infrastructure and no prior experience controlling Ebola.”); Colin McInnes, *The Many Meanings of Health Security*, in *ROUTLEDGE HANDBOOK OF GLOBAL HEALTH SECURITY* 7, 10 (Simon Rushton & Jeremy Youde eds., 2015) (“[Those states that] have had very high levels of infection for more than a decade, especially in sub-Saharan Africa[,] ... are ... among some of the poorest countries on earth.”); Morten Broberg, *A Critical Appraisal of the World Health Organization’s International Health Regulations (2005) in Times of Pandemic: It Is Time for Revision*, 11 *EUR. J. RISK REG.* 202, 208 (2020) (“[B]ecause states in the Global South, on average, have fewer resources to enable them to detect and respond to transmittable diseases at an early stage, there is a higher risk that if such diseases do break out, they may quickly become unmanageable in these country contexts.”); Yu, *Virotech Patents*, *supra* note 15, at 1652 (“[P]overty and a lack of infrastructure—whether in Asia, Africa, or other parts of the world—could create ‘weak links’ in the global response to pandemics.”).

133. As my colleagues at the Scowcroft Institute of International Affairs noted in their 2017 White Paper:

The problem of insufficient infrastructure is a global problem with

As dangerous as they can be, nationalist pandemic responses are also highly ineffective. Because global pandemics do not respect territorial borders,¹³⁴ nationalist approaches rarely provide effective policy responses. As the webpage for the Access to COVID-19 Tools Accelerator rightly reminded us, “[n]o-one is safe until everyone is safe.”¹³⁵ The need for international cooperation to promote domestic and global health security therefore cannot be overlooked.

implications for our homeland security. 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.

SCOWCROFT INST. OF INT’L AFFS., TEXAS A&M UNIV., *THE GROWING THREAT OF PANDEMICS: ENHANCING DOMESTIC AND INTERNATIONAL BIOSECURITY* 31 (2017); *see also* 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.”); Yu, *Virotech Patents*, *supra* note 15, at 1630 (calling for intellectual property negotiators to “realign their focus ... [away from] trade benefits ... [and] with greater security benefits within the global health system”).

134. As Colin McInnes observed:

Health threats, the provision of health care services and the market for pharmaceuticals are increasingly transborder in nature. In terms of health security, this makes defence “at the border” a near impossibility despite efforts by states to do just that. The state can no longer function as a self-contained vessel for health provision (and indeed health security), rather it has become permeable. This is most obviously the case with infectious disease where the processes of globalization have enabled disease to spread more quickly.

Colin McInnes, *National Security and Global Health Governance*, in *GLOBAL HEALTH GOVERNANCE: CRISIS, INSTITUTIONS AND POLITICAL ECONOMY* 42, 44 (Adrian Kay & Owain David Williams eds., 2009) (citation omitted); *see also* OBIJOFOR AGINAM, *GLOBAL HEALTH GOVERNANCE: INTERNATIONAL LAW AND PUBLIC HEALTH IN A DIVIDED WORLD* 6 (2005) (“Microbes carry no national passports, neither do they recognize geo-political boundaries or state sovereignty.”); DAVID P. FIDLER, *SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE* 13–16 (2004) (discussing the “germs do not recognize borders” mantra of public health); MARK W. ZACHER & TANIA J. KEEFE, *THE POLITICS OF GLOBAL HEALTH GOVERNANCE: UNITED BY CONTAGION* 1 (2008) (“The world is becoming an ever smaller place, and microbes that cause devastating diseases do not stop for border guards.”).

135. World Health Org., *The Access to COVID-19 Tools (ACT) Accelerator*, <https://www.who.int/initiatives/act-accelerator> [<https://perma.cc/6JPU-KUP4>] (last visited Sept. 11, 2020).

To some extent, policymakers and governments seem to be struck with a national pandemic response paradox:¹³⁶ while policymakers and governments know full well that global pandemics will necessitate cross-border solutions, the national public health crises steer their time, efforts, and energies toward developing policies to protect domestic constituents.¹³⁷ In this paradoxical policy environment, one logically wonders whether we could develop new models to better utilize the intellectual property system to address the global pandemic. One may also be curious about what global actions countries could take to enhance policy flexibilities and to more effectively address the highly diverse national and sub-national challenges posed by the global pandemic.

Although this Part does not have room to engage in a more extended discussion of the various international, national, and sub-national pandemic responses, some interesting models have emerged

136. Other commentators have identified similar paradoxes. For example, John Kraemer and Mark Siedner observed:

A central paradox of the West African Ebola epidemic is that, eventually, high-income countries and international organizations—especially the governments of the United States, the United Kingdom, Germany, and France, as well as the World Bank—expended enormous resources to control the epidemic.... [T]hose same resources are rarely made available to prevent epidemics, even though they would likely be more cost-effectively deployed then and could avert greater mortality.

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, *supra* note 94, at 55, 67 (footnote omitted); see also Peter G. Danchin et al., *The Pandemic Paradox in International Law*, 114 AM. J. INT'L L. 598, 599 (2020) (defining the “pandemic paradox” as “the fact that the COVID-19 pandemic has exposed the inherent logic and necessity of an effective international legal order at a moment when ideas of supranational organization and post-national sovereignty are increasingly resisted”); Mohamed S. El-Zomor & Amin R. Yacoub, *The Paradoxical Effect of COVID-19 on Globalisation*, OXPOL (Apr. 27, 2020), <https://blog.politics.ox.ac.uk/the-paradoxical-effect-of-covid-19-on-globalization/> [<https://perma.cc/TDJ7-DQWV>] (arguing that the COVID-19 pandemic “will set the stage for a potentially unprecedented era of global cooperation” despite having the tendency to intensify nationalism).

137. See RUSHTON, *supra* note 133, at 1 (“Because of politics, governments fail to cooperate internationally to prevent, detect and control outbreaks.”); see also JEREMY YOUDE, GLOBAL HEALTH GOVERNANCE 141 (2012) (“Securitization ... promotes short-term, us-versus-them thinking.”); Yu, *Virotech Patents*, *supra* note 15, at 1569 (noting the disconnect between the domestic and international debates on intellectual property and public health and the failure on the part of U.S. Congress and administration to synchronize domestic laws and policies with global developments).

in the past year. To illustrate the wide array of policy options and possibilities both within and outside the intellectual property system, this Part focuses on three widely praised initiatives.

In March 2020, Costa Rica advanced a proposal to create a patent pool of “technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.”¹³⁸ Building on the model that the Medicines Patent Pool utilizes¹³⁹ but going beyond its focus on patents and essential medicines,¹⁴⁰ the proposal stated:

This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, knowhow, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country.¹⁴¹

As part of its Solidarity Call to Action,¹⁴² the WHO embraced and operationalized Costa Rica’s proposal and formally named it the

138. Letter from Carlos Alvarado Quesada, President of Costa Rica, to Tedros Adhanom Ghebreyesus, Dir.-Gen., World Health Org. (Mar. 24, 2020), <https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf> [<https://perma.cc/9RUT-6VAV>] [hereinafter Costa Rica Proposal].

139. Established in July 2010 as a spinoff from Unitaid, a global health initiative financed by levies on plane tickets, the Medicines Patent Pool “aim[s] to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries through an innovative approach to voluntary licensing and patent pooling.” *About Us*, MEDICINES PATENT POOL, <https://medicinespatentpool.org/who-we-are/about-us/> [<https://perma.cc/RH49-X58X>] (last visited Aug. 15, 2020).

140. See William Worley, *COVID-19 Puts a Spotlight on the Medicines Patent Pool*, DEVEX (June 22, 2020), <https://www.devex.com/news/covid-19-puts-a-spotlight-on-the-medicines-patent-pool-97461> [<https://perma.cc/KX82-S6BB>] (“MPP [Medicines Patent Pool] ... has been [pooling technology] for a decade with patents, although not with other types of intellectual property that C-TAP plans to share, such as regulatory data. While there is not yet widespread agreement on how to make tools for beating COVID-19 accessible, MPP’s mandate has already been expanded to cover the illness.”); see also TRILATERAL STUDY, *supra* note 54, at 12 (“[W]ith the support of WHO and Unitaid, the Medicines Patent Pool has temporarily expanded its mandate to cover any COVID-19-related health technologies, including vaccines and diagnostics.”).

141. Costa Rica Proposal, *supra* note 138.

142. See *Making the Response to COVID-19 a Public Common Good: Solidarity*

COVID-19 Technology Access Pool.¹⁴³ Known for its abbreviation C-TAP, this technology pool is important because the technologies needed to address the global pandemic will likely involve multiple patent owners.¹⁴⁴ The pooling arrangement will therefore help prevent what commentators have called “patent thickets”¹⁴⁵ or “the tragedy of

Call to Action, WORLD HEALTH ORG. (June 1, 2020), <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action> [<https://perma.cc/WWU8-7LLY>] (requesting “key stakeholders and the global community to voluntarily pool knowledge, intellectual property and data necessary for COVID-19”).

143. See *COVID-19 Technology Access Pool*, WORLD HEALTH ORG., <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool> [<https://perma.cc/EE8M-7MGL>] (last visited Aug. 23, 2020) (“[C-TAP] compile[s], in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data.”); see also *WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19—29 May 2020*, WORLD HEALTH ORG. (May 29, 2020), <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---29-may-2020> [<https://perma.cc/9SZV-3N7P>] (identifying the five priorities of C-TAP).

144. As researchers from the Erasmus University Medical Center in the Netherlands surmised in relation to the patent pool proposal during the outbreak of the SARS coronavirus:

[In the absence of a patent pool, i]t is likely that patent rights incorporating the SARS genomic sequence will be fragmented across several groups. Sorting out these rights will be complex and may require intervention of the law court.... [For firms considering whether to develop a SARS vaccine], uncertainty over patent rights makes this decision even more difficult, because it is neither possible to determine the future cost of licensing the patent rights, nor whether all necessary patents will be available for licensing.... The incentive for vaccine manufacturers is therefore to delay the decision to invest.

H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 708 (2005).

145. See ELLEN F.M. ‘T HOEN, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH 90* (2009) (“Potential benefits of pooling include: a) reduced licensing transaction costs through ‘one stop’ licensing rather than multiple agreements; b) elimination of blocking patents; c) management of multiple owners and stacking of royalties”); Yu, *Virotech Patents*, *supra* note 15, at 1600 (“[P]atent pools provide an efficient and effective solution when patent rights are highly fragmented.”). Carl Shapiro defined a patent thicket as “a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.” Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119, 120

the anti-commons.”¹⁴⁶ The pool will further promote the research and innovation needed to address the global pandemic.¹⁴⁷ At the international level, the pool will also help promote the transfer of technology from developed to developing countries¹⁴⁸ while facilitating the greater integration of complementary technologies.¹⁴⁹

A month later, an international coalition of legal experts, scientists, and technologists released the Open COVID Pledge, which “calls on organizations around the world to make their patents and copyrights freely available in the fight against the COVID-19 pandemic.”¹⁵⁰ Among the masterminds behind this initiative is Jorge

(Adam B. Jaffe et al. eds., 2001).

146. Michael Heller and Rebecca Eisenberg defined the “the tragedy of the anti-commons” as a situation in which “multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use.” Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCI.* 698, 698 (1998); *see also* MICHAEL HELLER, *THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES* 49–78 (2010) (discussing the tragedy of the anti-commons in the biomedical research area).

147. *See* COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION & PUB. HEALTH, PUBLIC HEALTH, WORLD HEALTH ORG., *INNOVATION AND INTELLECTUAL PROPERTY RIGHTS* 53 (2006) (“Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries.”); *see also* Dianne Nicol & Jane Nielsen, *Opening the Dam: Patent Pools, Innovation and Access to Essential Medicines*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES* 235, 238 (Thomas Pogge et al. eds., 2010) [hereinafter *INCENTIVES FOR GLOBAL PUBLIC HEALTH*] (“Patent pooling may ... hold promise at the upstream discovery phase of the innovation cycle.”).

148. *See* FREDERICK M. ABBOTT & GRAHAM DUKES, *GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW’S WORLD* 39 (2011) (“Patent pools are sufficiently common as to have become subject to a fairly sophisticated level of regulation, for example, in the European Commission guidelines on technology transfer. Many of the issues surrounding the negotiation and implementation of patent pools already are anticipated by competition authorities.”); T HOEN, *supra* note 145, at 90 (pointing out that these pools have the potential to both “encompass non-patent technology and know-how” and “facilitate technology transfer and a sustainable scaling-up of capacity and access in the developing world”).

149. *See* U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY* § 5.5 (1995) (“[Patent pools] may provide procompetitive benefits by integrating complementary technologies ...”). *But see* Nicol & Nielsen, *supra* note 147, at 237 (“[Patent pools] could be both anti-competitive, particularly if they encourage collusion and shield weak patents, and anti-innovative (or innovation-neutral), particularly if they don’t include all necessary patents or are poorly managed and inadequately resourced.”).

150. OPEN COVID PLEDGE, <https://opencovidpledge.org/> [<https://perma.cc/7AQP-UP6P>] (last visited Aug. 26, 2020). For discussions of patent pledges, *see generally* PATENT PLEDGES (Jorge Contreras & Meredith Jacob eds., 2017); Jorge L. Contreras, *Patent Pledges*, 47 *ARIZ. ST. L.J.* 543 (2015).

Contreras, a contributor to this special issue. Since its creation, the Open COVID Pledge has attracted the support of Amazon, AT&T, Facebook, Fujitsu, Hewlett Packard, IBM, Intel, Microsoft, Mitsubishi, Uber, and other leading patent holders.¹⁵¹ At the time of writing, this timely pledge has already covered the following intellectual properties:

3D-printed respirators, touch screens that use ultraviolet light to prevent the spread of infection, a Wi-Fi enabled floating hospital, methods for designing grocery stores to ensure social distancing, a low-cost, single-use ventilator, software for accelerating disease diagnosis, algorithms for routing emergency vehicles through traffic, [and] a drive-up booth for Covid-19 testing.¹⁵²

This Open COVID Pledge built on the tireless efforts that policymakers, commentators, and activists have undertaken in the past two decades to show why open innovation can be highly beneficial in the public health arena, especially in relation to vaccine and drug development.¹⁵³ This pledge will greatly enhance the cooperation and collaboration among individuals, businesses, not-for-profit organizations, and government and intergovernmental agencies throughout the world. As Henry Chesbrough reminded us:

Opening up mobilizes knowledge from many different places, causing our learning to advance and our progress against the disease to accelerate. Openness unleashes a volunteer army of researchers, working in

151. *Pledgors*, OPEN COVID PLEDGE, <https://opencovidpledge.org/partners/> [<https://perma.cc/V25S-6HWY>] (last visited Sept. 12, 2020).

152. Jorge Contreras, *Putting Pledged IP to Work—Identifying IP Available Under the Open COVID Pledge*, OPEN COVID PLEDGE (June 12, 2020), <https://opencovidpledge.org/2020/06/12/putting-pledged-ip-to-work-identifying-ip-available-under-the-open-covid-pledge/> [<https://perma.cc/AMK4-VHNA>].

153. For discussions of open innovation in the pharmaceutical context, see generally GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 169–244 (Geertrui Van Overwalle ed., 2009); Krishna Ravi Srinivas, *Open Source Drug Discovery: A Revolutionary Paradigm or a Utopian Model?*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 147, at 263; Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017); Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005).

their own facilities, across different time zones, and different countries. Openness leverages the human capital available in the world to tackle the disease, and also accesses the physical capital (such as plant and equipment) already in place to launch rapid testing of possible solutions.

....

Open innovation can help speed things up. The availability of the gene sequencing of the coronavirus establishes a clear target to all of us. The 50+ vaccine candidates being considered are all already-approved drugs for other medical uses. This means that each candidate's basic safety dosage levels in humans have already been established. This allows the testing to start in the middle of the usual drug development process, with the Phase 1 safety protocols already completed. Releasing all the relevant medical research at once, in a machine-readable form that allows rapid absorption of the science, to anyone who wants to look at it, allows researchers from all over the world to contribute. And not just professional researchers and scientists, but also amateur researchers who have a passion and a hunch to test.¹⁵⁴

Finally, toward the end of April 2020, the WHO worked with Gavi and the Coalition for Epidemic Preparedness Innovations to launch the COVID-19 Vaccines Global Access (“COVAX”) Initiative.¹⁵⁵ This initiative aims to “accelerate the development and manufacture of COVID-19 vaccines ... and to guarantee fair and equitable access for every country in the world.”¹⁵⁶ The initiative's

154. Henry Chesbrough, *To Recover Faster from Covid-19, Open Up: Managerial Implications from an Open Innovation Perspective*, 88 *INDUS. MARKETING MGMT.* 410, 410–11 (2020); *see also* U.N. Sec'y-Gen.'s High-Level Panel on Access to Medicines, *supra* note 10, at 27 (“Open models of innovation, which are generally patent free and often rely on quick, straightforward licensing, ... [are] especially important to lower the hurdles of entry and accelerate the pace of development of health technologies, including those needed to combat emergent diseases.”).

155. *COVAX: Working for Global Equitable Access to COVID-19 Vaccines*, WORLD HEALTH ORG., <https://www.who.int/initiatives/act-accelerator/covax> [<https://perma.cc/L6QD-R5D3>] (last visited Aug. 18, 2020).

156. *Id.*

current target is to create two billion doses of COVID-19 vaccines that will be equitably distributed among the participating countries.¹⁵⁷ By July 2020, seventy-five countries had expressed interest in joining the COVAX Facility and “financ[ing] the vaccines from their own public finance budgets.”¹⁵⁸ The initiative will further allow these countries to “partner with up to 90 lower-income countries that could be supported through voluntary donations to Gavi’s COVAX Advance Market Commitment.”¹⁵⁹ As this special issue goes to print, the United States, under the new Biden Administration, has just announced its plan to join the COVAX Facility.¹⁶⁰

The launch of this global development and procurement initiative is badly needed as the world currently does not have the necessary capacity to manufacture vaccines for the entire global population.¹⁶¹ As South Africa rightly acknowledged in its general

157. See *COVAX Explained*, GAVI (Sept. 3, 2020), <https://www.gavi.org/vaccineswork/covax-explained> [https://perma.cc/2LNR-T8M3] (“All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as frontline healthcare workers.”).

158. Press Release, World Health Org., More Than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility (July 15, 2020), <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility> [https://perma.cc/C97B-FACB].

159. *Id.*

160. See Stephanie Nebehay, *U.S., Staying in WHO, to Join COVID Vaccine Push for Poor Nations: Fauci*, REUTERS (Jan. 21, 2021, 3:38 AM), <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/6JLQ-VK47] (providing a list of countries participating in the COVAX Initiative).

161. As a *Lancet* editorial noted:

To protect the global population, 6.2 billion doses of pandemic vaccine will be needed, but under current manufacturing capacity the world can only produce 500 million doses. And, in a pandemic, it is industrialised countries that will have access to available vaccines, whereas developing countries—where a pandemic is likely to emerge—will be left wanting. In November, 2004, a WHO consultation reached the depressing conclusion that most developing countries would have no access to vaccine during the first wave of a pandemic and possibly throughout its duration.

Editorial, *Global Solidarity Needed in Preparing for Pandemic Influenza*, 369 LANCET 532, 532 (2007) [hereinafter *Global Solidarity Needed*]; see also PEOPLE’S HEALTH MOVEMENT ET AL., GLOBAL HEALTH WATCH 2: AN ALTERNATIVE WORLD HEALTH REPORT 233 (2008) (“As drug companies can produce only a limited amount of vaccines in a given year, many developed countries have made advance

statement in the July 2020 meeting of the Council for Trade-Related Aspects of Intellectual Property Rights at the WTO:

The challenge before us is to produce an effective vaccine to meet the needs of the world population of 7.8 billion in as short a time frame as possible. This will require the sharing of knowledge and technology of successful vaccines so that the widest distribution at lowest cost can be achieved.¹⁶²

Even with its targeted two billion doses, the COVAX Initiative provides only a quarter of the vaccines needed for the entire global population. That number will be significantly lowered by a factor of multiples if the vaccine requires timed or regular boosters to create immunity.¹⁶³

The problem concerning global vaccine shortage is nothing new. For developing countries, it was a major issue during the H1N1 pandemic¹⁶⁴ as well as the earlier H5N1 avian influenza outbreak.¹⁶⁵ Indeed, the concerns about such shortage were so acute that Indonesia,

purchase orders for vaccines, limiting even further the prospects of countries like Indonesia benefiting from vaccine development.” (citation omitted)).

162. Nirmalya Syam, *WTO TRIPS Council Discusses National IP Measures and TRIPS Flexibilities in the Context of COVID-19* (S. Ctr., SouthNews No. 327, Aug. 7, 2020), <https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=184960e08b> [<https://perma.cc/X9Q2-HQD6>]; see also Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting—Held in the Centre William Rappard on 30 July 2020*, WTO Doc. IP/C/M/95/Add.1 (Oct. 2, 2020) (providing the minutes of the July 2020 meeting).

163. See Sarah Pitt, *A Coronavirus Vaccine May Require Boosters—Here’s What That Means*, CONVERSATION (July 29, 2020), <https://theconversation.com/a-coronavirus-vaccine-may-require-boosters-heres-what-that-means-143370> [<https://perma.cc/83AA-B28W>] (“[I]t currently seems likely that most potential vaccines designed to protect against the SARS-CoV-2 virus that causes COVID-19 will require boosters, perhaps regularly.”); Kevin Rawlinson, *More Data Needed Before Giving Just One Vaccine Dose, Says Covid Adviser*, GUARDIAN (Dec. 23, 2020 12:39 PM), <https://www.theguardian.com/world/2020/dec/23/more-data-needed-before-second-vaccine-dose-diverted-to-first-timers-says-covid-adviser> [<https://perma.cc/ED3E-LDMC>] (reporting the emerging debate on the sufficiency of a single, as opposed to double, dose of the currently approved vaccine).

164. See David P. Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1*, 7 PLOS MED. e1000247, at 1 (2010) (“Developed countries placed large advance orders for 2009-H1N1 vaccine and bought virtually all the vaccine companies could manufacture.”).

165. See *Global Solidarity Needed*, *supra* note 161 (expressing sympathy to the developing countries’ concern at the time of the H5N1 avian influenza outbreak about their lack of adequate and affordable access to pandemic vaccines).

India, Thailand, and other members of the Non-Aligned Movement¹⁶⁶ began asserting highly controversial claims of “viral sovereignty” to protect the virus samples they had collected from patients or animals on their soils.¹⁶⁷ Their wish to protect their own nationals and residents is no different from those policymakers who are now pushing for nationalist policies in the United States and other developed countries.

Moreover, as Ana Santos Rutschman noted in her contribution to this Symposium and in other articles written before the COVID-19 pandemic, vaccine development often requires different incentive frameworks and funding arrangements.¹⁶⁸ In developing countries,

166. Established during the cold war, the Non-Aligned Movement provides a forum for over 100 developing countries that do not align with any power bloc. See *History and Evolution of Non-Aligned Movement*, MINISTRY OF EXTERNAL AFFS. (Aug. 22, 2012), <https://www.mea.gov.in/in-focus-article.htm?20349/History+and+Evolution+of+NonAligned+Movement> [<https://perma.cc/7SH5-HC3P>] (providing the history of the Non-Aligned Movement).

167. See Yu, *Virotech Patents*, *supra* note 15, at 1604–18 (discussing the H5N1 avian influenza outbreak and the position taken by Indonesia and other countries). See generally VIRAL SOVEREIGNTY AND TECHNOLOGY TRANSFER: THE CHANGING GLOBAL SYSTEM FOR SHARING PATHOGENS FOR PUBLIC HEALTH RESEARCH (Sam Halabi & Rebecca Katz eds., 2020) (collecting articles that explore the implications of viral sovereignty claims to global biomedical research and issues relating to the control and sharing of pathogens and related data).

168. As Professor Santos Rutschman observed:

[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 vaccine-related patent applications increased, over time the number of new vaccines entering the market each year has remained relatively low.

Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 731 (2019); see also Rutschman, *Vaccine Markets*, *supra* note 93, at 111 (“Vaccines are often described as one of the most unprofitable types of biopharmaceutical goods, under-incentivized from a research and development ... perspective, and routinely failing to attract sufficient investment from traditional funders in biopharma.”). Xue Qiwei and Lisa Ouellette concurred:

[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. And IP [intellectual property]–based allocation is also ill-suited to the vaccine context,

efforts to distribute vaccines frequently encounter barriers that are unrelated to the intellectual property system;¹⁶⁹ inadequate public health infrastructure is the oft-documented culprit¹⁷⁰ behind the so-called “last-mile problem.”¹⁷¹ As WIPO Director General Francis Gurry reminded us, “there are many other policy challenges in the management of the COVID-19 crisis that are not directly related to [intellectual property] and innovation” and that do not involve the “question of [intellectual property] blocking access to vital medical vaccines, treatments or cures.”¹⁷²

Taken together, these three initiatives have shown that the debate on the modalities of protection is far from binary. While patents and regulatory exclusivities often come to mind when we explore the possible incentive frameworks to promote pharmaceutical innovation, there are many other policy options, incentive frameworks, and funding arrangements¹⁷³ both within and outside the intellectual

as illustrated most recently by the many calls to make any COVID-19 vaccine affordable and available to all.

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

169. See Yu, *The International Enclosure Movement*, *supra* note 18, at 853 (noting the need “to distinguish among the IP-relevant, IP-related, and IP-irrelevant factors and develop solutions that are tailored to each type of factor”).

170. See DAVIES, *supra* note 131, at 180 (“An inadequate number of health care workers to distribute the vaccine, community resistance, and the waxing and waning of donor interest all contribute to the premature end of vaccination projects.”); 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*, 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/95J7-23PA>] (“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.”); see also SCOWCROFT INST. OF INT’L AFFS., *supra* note 133, at 33 (“Diagnostics must be able to run without electricity and withstand temperature extremes and power surges, or they will be of limited use in many developing countries.” (citation omitted)).

171. Thomas Pogge, *The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 147, at 135, 141.

172. Gurry, *supra* note 107, ¶ 10.

173. Notable examples include open-source models, subsidies, grants, prizes, and advance market commitments. See Jorge L. Contreras, *Expanding Access to Patents for COVID-19*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 98, at 158, 158 (“In addition to patents, which reward inventors for financially successful

property system.¹⁷⁴ Thus, if we are to design effective policy responses to address a global pandemic, we will need to deploy a holistic and multidisciplinary approach to evaluate the different possibilities at the international, national, and sub-national levels.¹⁷⁵

V. CONCLUSION

The COVID-19 pandemic has shown us firsthand that countries will need different policy responses to address a global pandemic. What works for the northern hemisphere may not work well for the southern hemisphere, especially if seasonal changes will affect the pandemic at issue.¹⁷⁶ Likewise, what makes good policy sense in developed countries may generate bad or unintended consequences in the developing world.¹⁷⁷ Because the COVID-19 pandemic has posed

innovations, a range of other incentives such as prizes, grants, and subsidies ... exist to motivate technological innovation.”). For discussions of grants, prizes, and advance market commitments, see generally TRILATERAL STUDY, *supra* note 54, at 156–58; INCENTIVES FOR GLOBAL PUBLIC HEALTH, *supra* note 147, 135–208; Michael Kremer et al., *Designing Advance Market Commitments for New Vaccines*, HARV. SCHOLAR (Dec. 2019) https://scholar.harvard.edu/files/kremer/files/amc_design_36.pdf [<https://perma.cc/3YE8-52D4>].

174. As Amy Kapczynski observed:

IP scholarship has for decades been centered on a simple account: IP is necessary to achieve the information production that we as a society desire. But over the last few years, the field has come to recognize that IP as an approach has both significant costs and substantial limits. In response, an important new scholarly literature on “intellectual production without intellectual property,” or “IP without IP” has emerged.

Kapczynski, *supra* note 153, at 1542–43 (footnotes omitted); see also Yu, *A Half-Century of Scholarship*, *supra* note 75, at 1137 n.370 (collecting “IP without IP” scholarship).

175. See Yu, *Virotech Patents*, *supra* note 15, at 1621–27 (discussing the need for holistic, multidisciplinary, socio-legal analysis of intellectual property law and policy).

176. See A. Odysseus Patrick & Max Bearak, *Winter Is Coming South of the Equator, Along with Predictions of the Coronavirus’s Spread*, WASH. POST (June 6, 2020, 1:41 PM), https://www.washingtonpost.com/world/winter-is-coming-south-of-the-equator-along-with-predictions-of-the-coronavirus-spreading/2020/06/04/c0dd4c92-a4c9-11ea-898e-b21b9a83f792_story.html [<https://perma.cc/P22X-RFLD>] (“As countries in the Northern Hemisphere tilt into summer and emerge from months-long coronavirus shutdowns, winter arrives this month in subtropical parts of the Southern Hemisphere—and with it increased concern for the virus’s spread.”).

177. See Alex Broadbent, *South Africa’s Leaders Have Had a Crack at COVID-19: It’s Time to Give the People a Go*, CONVERSATION (July 16, 2020, 12:03 PM), <https://theconversation.com/south-africas-leaders-have-had-a-crack-at-covid-19-its-time-to-give-the-people-a-go-142573> [<https://perma.cc/B5AH-9CQE>] (“[T]he

diverse policy challenges at the international, national, and sub-national levels, it is high time we developed a deeper understanding of the different modalities of intellectual property protection, the interplay between these modalities, and the possibilities for incentive frameworks and funding arrangements outside the intellectual property system. It is my hope that this Symposium will help generate new ideas to improve the intellectual property system and to enhance its ability to address public health needs at both the domestic and international levels.

leadership of a Malawian village came up with a solution to protect older people by locating them in one part of the village. Malawi never locked down but, with a very poor population, half of whom are 17 or under, it is really not clear why it should.”); Alex Broadbent & Benjamin T.H. Smart, *Why a One-Size-Fits-All Approach to COVID-19 Could Have Lethal Consequences*, CONVERSATION (Mar. 24, 2020, 1:29 AM), <https://theconversation.com/why-a-one-size-fits-all-approach-to-covid-19-could-have-lethal-consequences-134252> [<https://perma.cc/5MVV-7S2Q>] (“In Africa, millions will starve if the global economy enters a protracted downturn. We must ask whether the number will be more than COVID-19 will kill in a region where only 6.09% of the population is over 65.”).