DATA EXCLUSIVITIES AND THE LIMITS TO TRIPS HARMONIZATION

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I. INTRODUCTION

When the Agreement on Trade-Related Aspects of Intellectual Property Rights[1] (TRIPS Agreement) was adopted in Marrakesh in April 1994, commentators marveled at its success in establishing international minimum standards for the protection and enforcement of intellectual property rights.[2] Apart from copyrights, patents, and

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1. 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].

2. As a World Trade Organization panel observed in the intellectual property enforcement area:

> The inclusion of [Part III] on enforcement in the TRIPS Agreement was one of the major accomplishments of the Uruguay Round negotiations as it expanded the scope of enforcement aspect of intellectual property rights. Prior to the

trademarks—the three main branches of intellectual property law—the TRIPS Agreement also harmonized the international standards for five additional categories of intellectual property rights—namely, trade secrets, geographical indications, industrial designs, layout designs of integrated circuits, and plant variety protections.[3]

Although these standards have greatly benefited countries exporting intellectual property–based goods and services—and, by extension, their intellectual property industries—policymakers in developing countries and their supporting commentators and nongovernmental organizations (NGOs) have widely criticized the TRIPS Agreement for imposing on developing countries "one size fits all" standards—or, more precisely, "supersize fits all" standards.[4] These high standards have created heavy economic burdens on these countries[5] while impeding their

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TRIPS Agreement, provisions related to enforcement were limited to general obligations to provide legal remedies and seizure of infringing goods.

Panel Report, *United States—Section 211 Omnibus Appropriations Act of 1998*, ¶ 8.97, WTO Doc. WT/DS176/R (adopted Aug. 6, 2001); *see also* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 440 (3d ed. 2008) ("The enforcement section of the TRIPS Agreement is clearly one of the major achievements of the negotiation."); U.N. CONFERENCE ON TRADE & DEV.–INT'L CTR. FOR TRADE & SUSTAINABLE DEV. PROJECT ON INTELLECTUAL PROP. RIGHTS & SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 629 (2005) [hereinafter TRIPS RESOURCE BOOK] ("The introduction of a detailed set of enforcement rules as part of TRIPS has been . . . one of the major innovations of this Agreement.").

3. *See* TRIPS Agreement, *supra* note 1, arts. 9-40 (establishing these standards).

4. *See* Shamnad Basheer & Annalisa Primi, *The WIPO Development Agenda: Factoring in the "Technologically Proficient" Developing Countries*, *in* IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION'S DEVELOPMENT AGENDA 100, 110 (Jeremy de Beer ed., 2009) [hereinafter IMPLEMENTING WIPO DEVELOPMENT AGENDA] (alluding to the "one-'super-size'-fits-all model"); Jeremy de Beer, *Defining WIPO's Development Agenda*, *in* IMPLEMENTING WIPO DEVELOPMENT AGENDA, *supra*, at 1, 3 (referring to "a one-size, especially a supersize, model of global [intellectual property] law"); James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9, at 3-4 ("One size fits all. And it is 'extra large.' ").

5. *See* Jagdish Bhagwati, *What It Will Take to Get Developing Countries into a New Round of Multilateral Trade Negotiations*, *in* CAN. GOV'T DEP'T FOREIGN AFFAIRS & INT'L TRADE, TRADE POLICY RESEARCH 2001, at 19, 21 (2001) ("TRIPS does not involve mutual gain; rather, it positions the WTO primarily as a collector of intellectual property–related rents on behalf of multinational corporations . . . ."); WORLD BANK, GLOBAL ECONOMIC PROSPECTS AND THE DEVELOPING COUNTRIES 2002: MAKING TRADE WORK FOR THE WORLD'S POOR xvii (2002) (estimating that "rent transfers to major technology-creating countries—particularly the United States, Germany, and France—in the form of pharmaceutical patents, computer chip designs, and other intellectual property, would amount to more than $20 billion"); Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 889 (2007) [hereinafter Yu, *The International Enclosure Movement*] (noting that the unquestioned adoption of foreign intellectual property standards "might . . . exacerbate the dire economic plight of less developed countries by allowing foreign rights holders to crush local industries through the threats of litigation, or even actual litigation"); J. Michael Finger, *The Doha Agenda and Development: A View from the Uruguay Round* 9 (Asian Dev. Bank, Econ. & Research Dep't Working Paper Series, Paper No. 21, 2002), https://www.adb.org/sites/default/files/publication/28316/wp021.pdf [https://perma.cc/XZ8Q-2S9H] (stating that "TRIPS developing countries took on as legal obligation a cost of $60 billion per year").

access to information, knowledge, and essential medicines.[6] In addition, the TRIPS standards have eroded their much-needed policy space to design an intellectual property system that is tailored to "local needs, national interests, technological capabilities, institutional capacities, and public health conditions."[7]

Regardless of one's perspective, the harmonization project advanced by the TRIPS Agreement,[8] and continued through TRIPS-plus bilateral, regional, and plurilateral agreements,[9] has been at the forefront of the international intellectual property debate. While this Article is interested in exploring this continuous, and continuously controversial, project at this well-timed juncture when the TRIPS Agreement celebrates its twenty-fifth anniversary, the discussion here will focus on a topic that international intellectual property scholars have underexplored: the limits to TRIPS harmonization.

To help examine these limits, this Article focuses on the protections for undisclosed test or other data for pharmaceutical and agrochemical products.[10] This focus is chosen for three reasons. First, until the adoption of the TRIPS Agreement, such protections "ha[ve] never been the

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6. *See* Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 370 (2006) ("The strong protection mandated under the TRIPs Agreement . . . threatens their much-needed access to information, knowledge, and essential medicines.").

7. Yu, *The International Enclosure Movement*, *supra* note 5, at 828; *see also* Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA*, 64 SMU L. REV. 975, 1037 (2011) ("[A]lthough promoting uniform rules may be beneficial, greater harmonization of legal standards could take away the valuable opportunities for experimentation with new regulatory and economic policies.").

8. For the Author's earlier discussions of these harmonization efforts, see generally Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 429-35 (2004) [hereinafter Yu, *Currents and Crosscurrents*]; Peter K. Yu, *The Harmonization Game: What Basketball Can Teach About Intellectual Property and International Trade*, 26 FORDHAM INT'L L.J. 218 (2003).

9. *See generally* INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS (Christopher Heath & Anselm Kamperman Sanders eds., 2007) (collecting essays that discuss free trade agreements in the intellectual property context); Robert Burrell & Kimberlee Weatherall, *Exporting Controversy? Reactions to the Copyright Provisions of the U.S.–Australia Free Trade Agreement: Lessons for U.S. Trade Policy*, 2008 U. ILL. J.L. TECH. & POL'Y 259 (criticizing the United States–Australia Free Trade Agreement); Yu, *Currents and Crosscurrents*, *supra* note 8, at 392-400 (discussing the growing use of bilateral and regional trade agreements to push for higher intellectual property standards).

10. *See* TRIPS Agreement, *supra* note 1, art. 39.3 (providing protections for undisclosed test or other data for pharmaceutical and agrochemical products). The definition of "test data" is obvious. As Carlos Correa pointed out: "Test data is the information generated to demonstrate the efficacy and safety of new chemical entities for use as pharmaceuticals or agrochemicals. In the case of pharmaceuticals, such data include the results of pre-clinical studies (pharmacodynamic, pharmacokinetic, and toxicological tests) and of phases 1 to 3 of clinical studies." CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 375 (2007). However, there is no standard definition of the term "other data." *See id.* at 377 (noting that " 'other data' may include . . . manufacturing, conservation, and packaging methods and conditions, but only to the extent that it is *necessary* to submit them in order to obtain marketing approval").

subject of any multilateral agreement."[11] Because no international minimum standards existed, the standards in that agreement provide a highly instructive example of the TRIPS harmonization project. Second, the protection of undisclosed test or other data remains highly controversial in recent international intellectual property negotiations. These negotiations include those involving the Trans-Pacific Partnership (TPP),[12] which has now become the Comprehensive and

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11. JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 4 (2001); *see also* CORREA, *supra* note 10, at 366 (noting that Section 7 of Part II of the TRIPS Agreement provides "the first international regime on undisclosed information," and describing the protection of undisclosed test or other data as "one of the most significant innovations brought about by the TRIPS Agreement"); GERVAIS, *supra* note 2, at 424 ("[The field] of what in various national laws may be called 'trade secrets', 'confidential information' or the like . . . is not regulated in multilateral conventions, apart from the general obligations in respect of unfair competition found in art.10*bis* of the Paris Convention." (footnote omitted)); TRIPS RESOURCE BOOK, *supra* note 2, at 522 ("TRIPS is the first international convention specifically imposing obligations on undisclosed information, including test data."); Peter K. Yu, *Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals*, 6 TEX. A&M L. REV. ARGUENDO 22, 23 (2018) [hereinafter Yu, *Data Exclusivities*] ("Article 39.3 provides the earliest multilateral protection for clinical trial data that have been submitted to regulatory authorities for the marketing approval of pharmaceutical products."). 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 EU member states provided exclusivity protection for the data filed in support of marketing authorization for pharmaceuticals since 1987.

TRIPS RESOURCE BOOK, *supra* note 2, at 522.

12. Trans-Pacific Partnership Agreement, Feb. 4, 2016 [hereinafter TPP Agreement], https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [https://perma.cc/AMZ6-Z3YC]. For the Author's discussions of the TPP, see generally Peter K. Yu, *The ACTA/TPP Country Clubs*, *in* ACCESS TO INFORMATION AND KNOWLEDGE: 21ST CENTURY CHALLENGES IN INTELLECTUAL PROPERTY AND KNOWLEDGE GOVERNANCE 258 (Dana Beldiman ed., 2013); Peter K. Yu, *TPP, RCEP, and the Crossvergence of Asian Intellectual Property Standards* [hereinafter Yu, *Crossvergence*], *in* GOVERNING SCIENCE AND TECHNOLOGY UNDER THE INTERNATIONAL ECONOMIC ORDER: REGULATORY DIVERGENCE AND CONVERGENCE IN THE AGE OF MEGAREGIONALS 277 (Peng Shin-yi et al. eds., 2018) [hereinafter GOVERNING SCIENCE AND TECHNOLOGY]; Peter K. Yu, *TPP, RCEP and the Future of Copyright Norm-setting in the Asian Pacific*, *in* MAKING COPYRIGHT WORK FOR THE ASIAN PACIFIC: JUXTAPOSING HARMONISATION WITH FLEXIBILITY 19 (Susan Corbett & Jessica C. Lai eds., 2018) [hereinafter Yu, *Copyright Norm-setting*]; Peter K. Yu, *Thinking About the Trans-Pacific Partnership (and a Mega-Regional Agreement on Life Support)*, 20 SMU SCI. & TECH. L. REV. 97 (2017) [hereinafter Yu, *Thinking About TPP*]; Peter K. Yu, *TPP and Trans-Pacific Perplexities*, 37 FORDHAM INT'L L.J. 1129 (2014).

Progressive Agreement for Trans-Pacific Partnership (CPTPP);[13] the Regional Comprehensive Economic Partnership (RCEP),[14] which is under negotiation between Australia, China, India, Japan, New Zealand, South Korea, and the Association of Southeast Asian Nations (ASEAN); [15] and the United States–Mexico–Canada Agreement (USMCA),[16] which was signed in November 2018 and will likely replace the North American Free Trade Agreement (NAFTA)[17] in the near future.[18] Third, many new issues have arisen in relation to the protection of undisclosed test or other data. Among these issues are the arrival of big-data analytics in research and development (R&D) for pharmaceutical and agrochemical products, the ongoing effort to develop international minimum standards for the protection of biologics,[19] China's innovative turn and its continued reforms in the patent and pharmaceutical areas,[20] and the increasing use of other international regulations and fora to address intellectual property disputes

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13. Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Mar. 8, 2018 [hereinafter CPTPP], https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-concluded-but-not-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text [https://perma.cc/37HP-EGTZ]; *see also* Yu, *Thinking About TPP*, *supra* note 12, at 104-06 (discussing the CPTPP); N.Z. Gov't Ministry Foreign Aff. & Trade, *CPTPP v. TPP*, https://www.mfat.govt.nz/en/trade/free-trade-agreements/agreements-under-negotiation/cptpp-2/tpp-and-cptpp-the-differences-explained/ [https://perma.cc/3UYA-2SNM] (explaining the differences between the TPP and the CPTPP).

14. *See* ASEAN Plus Six, Joint Declaration on the Launch of Negotiations for the Regional Comprehensive Economic Partnership (Nov. 20, 2012) [hereinafter Joint Declaration], https://dfat.gov.au/trade/agreements/negotiations/rcep/news/Documents/joint-declaration-on-the-launch-of-negotiations-for-the-regional-comprehensive-economic-partnership.pdf [https://perma.cc/CGP8-XHA4] (launching the RCEP negotiations).

15. For the Author's analysis of the RCEP, see generally Peter K. Yu, *The RCEP Negotiations and Asian Intellectual Property Norm Setters*, *in* THE FUTURE OF ASIAN TRADE DEALS AND INTELLECTUAL PROPERTY (Liu Kung-Chung & Julien Chaisse eds., forthcoming 2019) [hereinafter Yu, *Norm Setters*]; Yu, *Crossvergence*, *supra* note 12; Yu, *Copyright Norm-setting*, *supra* note 12; Peter K. Yu, *The RCEP and Trans-Pacific Intellectual Property Norms*, 50 VAND. J. TRANSNAT'L L. 673 (2017) [hereinafter Yu, *RCEP and Trans-Pacific Norms*]. The ten ASEAN members are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam. *Member Countries*, ASS'N SE. ASIAN NATIONS, https://asean.org/asean/asean-member-states/ [https://perma.cc/JD8Y-ADEW].

16. United States–Mexico–Canada Agreement, Can.-Mex.-U.S., Nov. 30, 2018 [hereinafter USMCA], https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement [https://perma.cc/N3GZ-YR7N].

17. North American Free Trade Agreement, Can.-Mex.-U.S., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

18. *See* Glenn Thrush, *Trump Says He Plans to Withdraw from Nafta*, N.Y. TIMES (Dec. 2, 2018), https://www.nytimes.com/2018/12/02/us/politics/trump-withdraw-nafta.html [https://perma.cc/6M8T-4PP5] (reporting President Trump's announcement of his intention to withdraw the United States from NAFTA).

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

20. *See* discussion *infra* Section IV.B.

and questions.[21] Taken together, all of these TRIPS and TRIPS-plus developments provide important insights into the efforts to develop international minimum standards for the protection of undisclosed test or other data in the past twenty-five years.

Part II of this Article briefly revisits the TRIPS negotiations under the Uruguay Round of Multilateral Trade Negotiations (Uruguay Round).[22] This Part focuses on issues on which the TRIPS negotiating parties had achieved consensus or had failed to do so. It further discusses the tensions and conflicts between members of the World Trade Organization (WTO), using as an illustration the TRIPS dispute between Argentina and the United States over the inadequate protection of undisclosed test or other data.[23]

Part III turns to the development of TRIPS-plus bilateral, regional, and plurilateral agreements. This Part examines the negotiation of new international minimum standards for the protection of undisclosed test or other data. Although the early bilateral agreements initiated by the United States in the mid-2000s included treaty language enhancing such protection,[24] this Part focuses on the three latest regional or plurilateral agreements: the TPP Agreement, the proposed RCEP Agreement, and the recently signed USMCA.

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21. *See* discussion *infra* Section IV.C.

22. *See generally* GERVAIS, *supra* note 2, at 3-27 (describing the origins and development of the TRIPS Agreement); DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT (2002) (examining the role of intellectual property industries in the TRIPS negotiations); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 96-120 (2003) (recounting the trilateral intellectual property discussions among the United States, the European Union, and Japan); WATAL, *supra* note 11, at 11-47 (recounting the negotiation process for the TRIPS Agreement); Yu, *TRIPS and Its Discontents*, *supra* note 6, at 371-79 (examining four different accounts of origins of the TRIPS Agreement).

23. *See* Request for Consultations by the United States, *Argentina—Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, WTO Doc. WT/DS171/1 (May 10, 1999) [hereinafter *WTO Complaint 1*]; Request for Consultations by the United States, *Argentina—Certain Measures on the Protection of Patents and Test Data*, WTO Doc. WT/DS196/1 (June 6, 2000) [hereinafter *WTO Complaint 2*]. *See generally* KENNETH C. SHADLEN, COALITIONS AND COMPLIANCE: THE POLITICAL ECONOMY OF PHARMACEUTICAL PATENTS IN LATIN AMERICA 63-87, 141-67 (2017) (discussing the changing political landscape surrounding the push for greater protection for pharmaceutical patents in Argentina).

24. *See, e.g.*, Dominican Republic–Central America Free Trade Agreement, art. 15.10.1, Aug. 5, 2004 [hereinafter CAFTA–DR], http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text [https://perma.cc/P24B-TS8P]; United States–Australia Free Trade Agreement, Austl.-U.S., art. 17.10.1, May 18, 2004 [hereinafter U.S.–Australia FTA], https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text [https://perma.cc/YA7V-3BWS]; United States–Singapore Free Trade Agreement, Sing.-U.S., art. 16.8.1, May 6, 2003 [hereinafter U.S.–Singapore FTA], https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text [https://perma.cc/U95Z-NZMG].

To provide a holistic perspective, Part IV goes beyond the traditional discussion of TRIPS and TRIPS-plus treaty negotiations to identify three sets of additional complications that have affected developments at both the multilateral and nonmultilateral levels. This Part examines 1) the arrival of new technologies, such as the use of big-data analytics in R&D and the growing importance and popularity of biologics and personalized medicines; 2) the arrival of new politics, such as China's changing position in the patent and pharmaceutical areas and the recent amendments to its patent laws and pharmaceutical regulations; and 3) the arrival of new spillovers of regulatory standards from international regimes lying outside the intellectual property area, such as trade, investment, and data governance.

Part V concludes by drawing six distinct lessons regarding the TRIPS harmonization project. While the analysis in this Article could be interpreted as either strengthening or weakening this project, depending on whether one looks at the TRIPS Agreement as a glass half full or a glass half empty, this Article aims to offer a more cautious and nuanced assessment of the TRIPS Agreement's ability to facilitate the international harmonization project. After all, there has been no better time than the Agreement's silver anniversary to take stock of the strengths and weaknesses of this project.

II. TRIPS AGREEMENT

The TRIPS Agreement was adopted in Marrakesh in April 1994. As stated in its preamble, the Agreement was established to achieve three key objectives.[25] First, it lays out the "adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights."[26] Second, the Agreement provides "effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems."[27] Third, the Agreement institutes "effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments."[28]

25. TRIPS Agreement, *supra* note 1, pmbl., recital 2. In addition to these three objectives, Recital 2 recognizes "the need for new rules and disciplines concerning . . . the applicability of the basic principles of GATT [General Agreement on Tariffs and Trade] 1994 and of relevant international intellectual property agreements or conventions . . . [and] transitional arrangements aiming at the fullest participation in the results of the negotiations." *Id.*

26. *Id.* recital 2(b).

27. *Id.* recital 2(c).

28. *Id.* recital 2(d).

Although Section C will implicate the mandatory WTO dispute settlement process,[29] this Part focuses primarily on the development of protection standards, and more specifically on those concerning undisclosed test and other data for pharmaceutical and agrochemical products. Section A explores the issues on which the TRIPS negotiating parties achieved consensus. Section B turns to the various areas in which the TRIPS language remains highly contested and in which the TRIPS negotiating parties eventually failed to achieve any international consensus. To further illustrate the significant disagreement between these parties during the TRIPS negotiations, Section C examines a key dispute between Argentina and the United States over the lack of protections for undisclosed test or other data for pharmaceutical and agrochemical products.

A. Consensus

As Jayashree Watal, a former TRIPS negotiator for India who now works in the WTO Intellectual Property, Government Procurement and Competition Division, observed, the protection of undisclosed information "has never been the subject of any multilateral agreement" until the adoption of the TRIPS Agreement.[30] Such information includes the test or other data that pharmaceutical and agrochemical companies are legally required to submit to regulatory authorities for marketing approval of their products.[31] While the submitted data are confidential, proprietary, and highly valuable, the authorities need them to evaluate the products' safety and efficacy. Should the pharmaceutical and agrochemical companies not submit the requested data, they will be unable to secure the needed approval to market their products. Should they comply with the request, however, their competitors may take unfair commercial advantage of their proprietary data.[32]

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29. For the Author's discussions of the WTO dispute settlement process, see generally Peter K. Yu, *The Comparative Economics of International Intellectual Property Agreements*, *in* COMPARATIVE LAW AND ECONOMICS 282, 298-309 (Theodore Eisenberg & Giovanni B. Ramello eds., 2016); Peter K. Yu, *State-to-State and Investor-State Copyright Dispute Settlement*, *in* LES RECOURS EN MATIÈRE DE DROIT D'AUTEUR (Ysolde Gendreau ed., forthcoming 2019); Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT'L L. & FOREIGN AFF. 311, 333-36 (2011) [hereinafter Yu, *TRIPS Game*].

30. WATAL, *supra* note 11, at 4.

31. *See* 21 U.S.C. § 355(b)(1) (2018) ("Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application . . . full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . .").

32. As the European Commission observed:

> Proponents of data exclusivity, as it exists in the [European Community] or the US, defending the interests of the R&D based pharmaceutical industry, argue that Article 39.3 was intended to prevent generic manufacturers from relying

Protection is therefore needed for undisclosed test or other data submitted to regulatory authorities.

To provide protection for these data, Article 39.1 states that, "[i]n the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect . . . data submitted to governments or governmental agencies in accordance with paragraph 3."[33] Article 39.3 further provides:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.[34]

The first sentence of Article 39.3 focuses on the obligation to protect "against unfair commercial use."[35] Based on the provision's ordinary meaning, this obligation will not arise unless five conditions have been met. First, to warrant protection, the test or other data at issue must be undisclosed—or, more properly worded, undisclosed to the public[36] at the time of submission.[37] Second, the protection is available to data

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> upon the originator's data as a "shortcut" to marketing approval, by giving the originator exclusive use of its data for a period of time sufficient for it to recoup the costs incurred in running trial tests and producing and compiling data for submission to regulatory authorities.

EUROPEAN COMM'N, COMPULSORY LICENSING AND DATA PROTECTION 18 (2006), https://www.concurrences.com/IMG/pdf/eu_-_compulsory_licensing.pdf?39810/b1edc6f4e4e32aff8c6f72eb553b3fcac28be6c1 [https://perma.cc/D3NE-4EJ4].

33. TRIPS Agreement, *supra* note 1, art. 39.3.

34. *Id.*

35. *Id.*; *see also* CORREA, *supra* note 10, at 381 ("The ordinary meaning of 'unfair' is '*not equitable or honest or impartial or according to rules*'. In the case of Article 39.3, this concept must be understood in the light of Article 10*bis* of the Paris Convention." (quoting CONCISE OXFORD DICTIONARY (7th ed. 1982)) (footnote omitted)).

36. As Daniel Gervais explained:

> The expression used in the Agreement, i.e. "undisclosed information" was chosen to avoid referring to an expression linked to a given legal system. The result may be misleading, however, because what is protected is not really "undisclosed" information (since, if no one has disclosed it to anyone, it could not be used at all), but rather information disclosed selectively and under precise conditions.

GERVAIS, *supra* note 2, at 424.

37. *See* G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L L. & BUS. 1, 35 (2003) ("TRIPS Article 39.3 only requires that the data be undisclosed as of the date of submission. There is no express condition that the data remain undisclosed after submission in order to maintain protection.").

for pharmaceutical or agrochemical products only.[38] Third, the products involved have to "utilize new chemical entities"[39]—a term that has intentionally been left undefined at the TRIPS negotiations[40] but has since become quite controversial in the developing world.[41] Fourth, the test data have to be submitted "as a condition of approving the marketing of" these products,[42] not on a voluntary basis.[43] Finally, the origination of the protected data has to "involve[] a considerable effort,"[44] somewhat akin, but not necessarily identical, to the requirement of "a substantial investment" in the EU Database Directive.[45]

The second sentence of Article 39.3 of the TRIPS Agreement focuses on the obligation to protect against the disclosure of submitted test or other data.[46] This obligation is similar to the obligation laid down in Article 1711.6 of NAFTA, which states that "no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during

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38. *See* TRIPS Agreement, *supra* note 1, art. 39.3 (covering only test or other data that have been submitted "as a condition of approving the marketing of pharmaceutical or of agricultural chemical products").

39. *Id.*

40. *See* CORREA, *supra* note 10, at 379 ("The TRIPS Agreement has deliberately avoided defining the concept of 'new chemical entity', thus deferring such definition to national law. This is one of the clear areas in which Member countries enjoy room for manoeuvre to implement the Agreement's provisions."); *see also* WATAL, *supra* note 11, at 7 (advancing the concept of "constructive ambiguity").

41. *See* Srividhya Ragavan, *Data Exclusivity: A Tool to Sustain Market Monopoly*, 8 JINDAL GLOBAL L. REV. 241, 252-55 (2017) [hereinafter Ragavan, *Data Exclusivity*] (noting the controversy surrounding the term "new chemical entities"); *see also* GERVAIS, *supra* note 2, at 427 ("[T]here could . . . be significant divergences of views on the precise meaning of 'new chemical entities', in particular as regards their novelty." (footnote omitted)). The word "new" nonetheless suggests that Article 39.3 does not grant protection to "existing chemical entities that have been reformulated or sold for a new indication." Robert Weissman, *Data Protection: Options for Implementation*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 151, 166 (Pedro Roffe et al. eds., 2006) [hereinafter NEGOTIATING HEALTH].

42. TRIPS Agreement, *supra* note 1, art. 39.3.

43. *See* CORREA, *supra* note 10, at 377 ("[T]he submission of data must be *necessary* to obtain approval. This means that data voluntarily submitted by an applicant, or in excess of those required for approval, are not subject to protection.").

44. TRIPS Agreement, *supra* note 1, art. 39.3; *see also* CORREA, *supra* note 10, at 379 ("The requirement of a 'considerable effort' suggests that national authorities may request the applicant to prove that the information for which protection is sought is the result of such effort."); GERVAIS, *supra* note 2, at 428 ("In many cases (e.g. clinical trials), there will be no doubt as to the sufficiency of the efforts necessary to generate the data.").

45. *See* Council Directive 1996/9, art. 7(1), 1996 O.J. (L 77) 20 (EC) (offering sui generis protection to databases that are created as a result of "a substantial investment in either the obtaining, verification or presentation of the [database] contents"); *see also* CORREA, *supra* note 10, at 380 ("Quite obviously, the proponents of th[e] formulation [requiring a 'considerable effort'] aimed at the protection of the *investment* made in producing the test data.").

46. *See* TRIPS Agreement, *supra* note 1, art. 39.3.

a reasonable period of time after their submission."[47] If the submitted data are to be disclosed, Article 39.3 of the TRIPS Agreement requires WTO members to meet one of the following two conditions. First, the disclosure is permitted if it is "necessary to protect the public."[48] This necessity requirement is similar to what is found in Article XX of the General Agreement on Tariffs and Trade.[49] Second, WTO members may disclose the submitted data if "steps [have been] taken to ensure that the data are protected against unfair commercial use."[50] These protective steps help fulfill the primary objective of the first sentence of Article 39.3.

Finally, for either the first or second sentence of Article 39.3, the TRIPS Agreement does not lay down any standard regarding the duration of protection.[51] The lack of such standard stands in sharp contrast to the language found in NAFTA and other TRIPS-plus bilateral, regional, and plurilateral agreements. Article 1711.6 of NAFTA explicitly states:

> [A] reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking

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47. NAFTA, *supra* note 17, art. 1711.6.

48. TRIPS Agreement, *supra* note 1, art. 39.3; *see also* CORREA, *supra* note 10, at 380 ("According to the interpretation of [the 'necessity test'] in other contexts of GATT/WTO rules, deference should be given to Members to determine when such necessity arises, but the Member invoking it will bear the burden of proof, an often difficult task.").

49. General Agreement on Tariffs and Trade art. XX, Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 188; *see also* Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement*, 45 HARV. INT'L L.J. 443, 450-52 (2004) (discussing the necessity requirement in Article 39.3 of the TRIPS Agreement). As a WTO document explained:

> Necessity tests establish the WTO consistency of a measure based on whether the measure is "necessary" to achieve certain policy objectives. These tests reflect the balance in WTO agreements between two important goals: preserving the freedom of Members to set and achieve regulatory objectives through measures of their own choosing, and discouraging Members from adopting or maintaining measures that unduly restrict trade. Necessity tests typically achieve this balance by requiring that measures, which restrict trade in some way (including by violating obligations of an agreement) are permissible only if they are "necessary" to achieve the Member's policy objective. In so doing, the necessity tests confirm the right of Members to regulate and to pursue their policy objectives.

World Trade Organization, *Note by the Secretariat: "Necessity Tests" in the WTO*, ¶ 4, WTO Doc. S/WPDR/W/27 (Dec. 2, 2003).

50. TRIPS Agreement, *supra* note 1, art. 39.3.

51. *See id.* (refraining from specifying the duration of protection); *see also* CORREA, *supra* note 10, at 380 ("Article 39.3 aims to preserve the confidentiality of the information submitted for marketing approval without any time limit. There is no indication in the provision about the duration of the obligation, certainly a weak point in the text."); GERVAIS, *supra* note 2, at 424 ("The [TRIPS] Agreement does not specify a time period.").

> account of the nature of the data and the person's efforts and expenditures in producing them.[52]

As the next Section will show, the NAFTA-like standard—"for a reasonable time, generally no less than five years"—was included in the 1990 Brussels draft of the TRIPS Agreement but was later removed as part of a compromise between developed and developing countries.[53] Commentators have also criticized the arbitrariness of the five-year period.[54] As Aaron Fellmeth observed:

> Five years of data exclusivity may not be enough to compensate the drug developer adequately for products requiring the most complex and extensive testing (which is why most European states grant ten years of exclusivity), while five years may be excessive for the straightforward testing associated with the most profitable drugs (which means that the harm caused by the European standard is doubly egregious in those situations). A predetermined, uniform monopoly period is a very blunt policy instrument because it treats all drug marketing approval efforts alike when, in fact, they may vary significantly.[55]

B. Contestation[56]

Notwithstanding the carefully drafted language in Article 39.3, the provision does not include all of the language demanded by developed countries and their pharmaceutical and agrochemical industries. To these countries, greater protection of undisclosed test or other data is important because it would provide additional incentives for R&D while increasing the countries' competitive and comparative advantage.[57] Nevertheless, commentators have questioned the need for

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52. NAFTA, *supra* note 17, art. 1711.6.

53. TRIPS RESOURCE BOOK, *supra* note 2, at 525.

54. *See* Fellmeth, *supra* note 49, at 478 (noting that "the five-year period [in NAFTA] is entirely arbitrary").

55. *Id.* at 478-79.

56. This Section features materials expanded from Yu, *Data Exclusivities*, *supra* note 11, at 23-26.

57. As I noted in an earlier article:

> As the pharmaceutical industry has claimed, "the development and bringing to market of a new drug requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing, at an average cost of US$800 million, and taking 10 to 15 years to complete." Because of the high costs of data collection and the large amount of time involved, additional protection, other than what pharmaceutical manufacturers already received under the patent system, is necessary to protect their investment. Such protection would also prevent third parties, in particular generic competitors, from free riding on the originator's efforts in collecting data during clinical trials. Viewed in

such protection.[58] For countries without a strong pharmaceutical or agrochemical industry, greater protection of such data could be highly detrimental. In the case of pharmaceutical products, for example, greater protection of undisclosed test or other data would increase healthcare costs, reduce access to medicines, and delay market entry of generic drugs.[59] Such protection would not only jeopardize public health[60]—at

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> this light, data exclusivity laws are less important as a means to generate incentives than for its ability to effectively erect a market entry barrier that extends the originator's limited monopolies.

Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 784 (2010) [hereinafter Yu, *Political Economy*] (footnote omitted) (quoting INT'L FED'N OF PHARM. MFRS. & ASS'NS, A REVIEW OF EXISTING DATA EXCLUSIVITY LEGISLATION IN SELECTED COUNTRIES 3 (4th rev. ed. 2005)); *see also* Carlos María Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 69 (2002) ("The rationale for [the data] exclusivity model is to permit the originator of data to recover the investments made for his development. The underlying assumption is that, without such protection, private firms would have no incentive to bear the considerable costs of producing the required data."); Skillington & Solovy, *supra* note 37, at 12-15 (discussing the benefits of providing protection to undisclosed test or other data for pharmaceuticals).

58. As Srividhya Ragavan declared:

> Th[e] logic [that the first drug applicant needs incentives to conduct clinical trials] stands on shaky grounds considering that [this] applicant typically seeks patent protection which, if successful, leads to monopoly profits during the statutory period of exclusivity meant to recoup research and other expenses. Clinical trials are conducted to determine whether the innovated [new chemical entity], for which a patent is filed, is safe to be marketed as a drug. Conducting clinical trials is therefore a part of the risk that innovator companies undertake in order to gain the enormous market benefits that come with patent protection.

Ragavan, *Data Exclusivity*, *supra* note 41, at 250-51.

59. As I noted in an earlier article:

> If pharmaceuticals become readily available at the end of the patent term, it will be inhumane to delay the entry of competitive drugs, whether on-patent or generic. Such delay, along with the reduced price competition, is likely to prolong, or even exacerbate, the massive public health crises in less developed countries.

Yu, *Political Economy*, *supra* note 57, at 785.

60. As Aaron Fellmeth observed:

> [T]here is the question of whether disclosure and nonexclusivity practices endanger public health. Disclosure of marketing approval data honors the public's interest in being informed about the safety and effectiveness of an approved drug and allows independent observers, such as academics and public interest groups, to conduct further testing and to verify or dispute the accuracy and impartiality of the data submitted by the registrant. It is sometimes observed that drug developers have an incentive to suppress unfavorable results from their drug testing or to exaggerate their efficacy findings. The lack of access to testing data seriously impedes third parties from uncovering bias, inaccurate or incomplete results, and false claims based on that data. The public may thereby be defrauded and public health exposed to unnecessary danger. By refusing to disclose drug testing information, the drug regulatory authority may prevent the discovery of undetected side effects, dangers, counterindications, or even the inefficacy

both the domestic and global levels[61]—but it would also raise ethical questions about unnecessary or duplicative testing.[62]

To a large extent, the specific language chosen for Article 39.3 reflects the difficult compromise struck between developed and developing countries.[63] During the TRIPS negotiations, two areas were highly

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> of an approved drug. Whether such independent assessment is "necessary to protect the public" may be arguable in any given instance, but disclosure is certainly more helpful to that end than nondisclosure.

Fellmeth, *supra* note 49, at 475-76 (footnotes omitted); *see also* Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 MISS. L.J. 705, 721-35 (2009) (discussing pharmaceuticals-related controversies involving allegations of suppression or misrepresentation of clinical trial data); Yu, *Political Economy*, *supra* note 57, at 786 ("In countries suffering from rampant corruption and a lack of government transparency, the public availability of these data and the possibility of using them to conduct independent evaluation are likely to be very important.").

61. *See* Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1627-30 (2013) [hereinafter Yu, *Virotech Patents*] (discussing how a public health issue in a developing country can be transformed into a global security issue).

62. As Professor Fellmeth declared:

> [D]uplicative testing is worse than wasteful—it is unethical. Animal testing of drugs causes the suffering and death of many millions of animals every year. Duplicative research caused by lack of access to confidential marketing approval data increases the number of animals unnecessarily subjected to testing. It may also subject humans to suffering in the form of side effects or prolonged unameliorated symptoms where some indications of the drug, though known to the drug regulatory authority by virtue of a prior registration for the drug, remain unknown to the subsequent applicant.

Fellmeth, *supra* note 49, at 474 (footnote omitted); *see also* Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements* [hereinafter Correa, *Protecting Test Data*], *in* NEGOTIATING HEALTH, *supra* note 41, at 81, 93 (noting the negative ethical implications of unnecessary duplication of preclinical and clinical trials); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 605 (3d ed. 2010) ("[N]ot only is repetition of tests a waste of scarce resources, but also, some tests should not be repeated at all, because they put at risk the lives and cause the suffering of animals and humans. Repetition of those tests is therefore more than wasteful: it is unethical."); Srividhya Ragavan, *The (Re)Newed Barrier to Access to Medication: Data Exclusivity*, 51 AKRON L. REV. 1163, 1189 (2017) [hereinafter Ragavan, *(Re)Newed Barrier*] ("Clinical trials are costly not just financially but also in terms of the patient suffering. . . . [T]he administering of the drug as part of the trial to wrong patient groups can lead to detrimental side effects."); Yu, *Political Economy*, *supra* note 57, at 785 (noting that it is "wasteful and highly undesirable to require duplicative testing in countries that have very limited economic resources," and that it is "immoral to require the use of human subjects and animals to retest drugs that are considered bioequivalent to those that have already been approved for the market").

63. As Professor Correa recalled:

> [I]n its starting positions in the TRIPS negotiations, developing countries rejected any form of protection for know-how under the Agreement. At the other extreme, proposals were made by some industrialized countries in order to establish a minimum period of exclusive protection (five years for pharmaceuticals) for the protection of the tests and data submitted for marketing approval. The

contested and eventually paved the way for the establishment of new international norms through TRIPS-plus bilateral, regional, and plurilateral agreements. The first area concerns whether regulatory authorities can rely on the originator's previously submitted test or other data when determining whether to grant marketing approval of follow-on pharmaceutical and agrochemical products.[64] Such reliance occurs when these authorities approve new products based on evidence provided by bioequivalence studies.[65] To prevent follow-on developers from free riding on the originator's submitted data, Article 1711.6 of NAFTA creates a separate obligation for prohibiting data reliance:

> Each Party shall provide that for data . . . that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's

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> text in the Agreement represents a compromise that leaves considerable room for implementation at the national level.

CORREA, *supra* note 10, at 376.

64. *See id.* at 381 ("One of the crucial interpretative issues in Article 39.3 is whether the reliance by a national authority on data submitted by one company (the 'originator')[,] to evaluate a subsequent application by another company (a 'follower'), constitutes an 'unfair commercial use' of the information."); GERVAIS, *supra* note 2, at 428 ("The practice of generic drug manufacturers who rely on the fact that a pharmaceutical product is approved and who only have to show the bio-equivalence of their own product could come under scrutiny, although some national courts have taken the view that such *reliance* (on alleged bio-equivalency) is not 'use'.").

65. As the Federal Food, Drug, and Cosmetic Act stated:

> A drug shall be considered to be bioequivalent to a listed drug if—
>
> (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or
>
> (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8)(B) (2018); *see also* Joan Rovira, *Creating and Promoting Domestic Drug Manufacturing Capacities: A Solution for Developing Countries?*, *in* NEGOTIATING HEALTH, *supra* note 41, at 227, 234 (discussing bioequivalence studies for anti-hypertensive and anti-inflammatory drugs in Colombia).

> efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.[66]

Unlike NAFTA, the TRIPS Agreement does not include explicit language mentioning data reliance.[67] When the TRIPS negotiators met in Brussels in December 1990, that draft contained the following bracketed language:

> 4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products . . . , the submission of undisclosed test or other data, the originator of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.[68]

This NAFTA-inspired bracketed language did not make it to the final text of the TRIPS Agreement.[69]

Drawing on this important piece of negotiating history, and utilizing an interpretive approach endorsed by the Vienna Convention on the Law of Treaties,[70] one can fairly state that the TRIPS negotiating parties did not achieve consensus over the data reliance issue.[71] Indeed, the removal of the Brussels draft language strongly supports the view that the TRIPS Agreement does not prohibit regulatory authorities from relying on previously submitted test or other data. As Jerome Reichman declared emphatically:

> To ignore the clear evolution of the text in favour of quasi-exclusive rights in regulatory data, in a form that was proposed but ultimately excised from the 1994 Final Act, would in effect amount to imposing

66. NAFTA, *supra* note 17, art. 1711.6.

67. *Compare id.*, *with* TRIPS Agreement, *supra* note 1, art. 39.3.

68. TRIPS RESOURCE BOOK, *supra* note 2, at 525.

69. TRIPS Agreement, *supra* note 1, art. 39.3.

70. *See* Vienna Convention on the Law of Treaties art. 32, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331 (entered into force Jan. 27, 1980) ("[I]ncluding the preparatory work of the treaty and the circumstances of its conclusion" as "supplementary means of interpretation").

71. For two very different accounts concerning the negotiation of Article 39.3 of the TRIPS Agreement, compare Fellmeth, *supra* note 49, at 454-60, with Skillington & Solovy, *supra* note 37, at 15-21.

> unbargained-for trade concessions beyond what was agreed in TRIPS without any legal foundation whatsoever.[72]

Moreover, the use of bioequivalence studies to grant marketing approvals does not always require the use or disclosure of previously submitted test or other data. As Professor Reichman continued:

> [I]t is not the confidential data themselves that are being unfairly used, even if a first comer is compelled to submit them in order to meet health and safety requirements. It is the health and safety outcome to which the data lead that is being used (a matter of public record) . . . .[73]

Although Professor Reichman made this observation in the mid-2000s, it is particularly relevant to today's emerging big-data environment, which Section IV.A further discusses. In this new technological environment, what is highly valuable are the collected test data and their ability to provide a large and comprehensive dataset[74]—not so much the specific health and safety outcomes proven by those data. Indeed, any follow-on developers seeking to use or reuse these data in a big-data environment will have to either generate the test data themselves or secure a license to use the originators' data. Having the specific health and safety outcomes alone will not meet their needs.

As if these issues were not complicated enough, many jurisdictions still do not require the submission of test data to secure the marketing approval of pharmaceutical and agrochemical products. As Carlos Correa observed, in these jurisdictions, "in order to obtain the registration of a similar product it was sufficient to prove that it had been approved

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72. Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?*, *in* NEGOTIATING HEALTH, *supra* note 41, at 133, 140 [hereinafter Reichman, *Undisclosed Clinical Trial Data*]; *see also* Public Citizen, *Data Exclusivity in the Regional Comprehensive Economic Partnership (RCEP)* 2, https://www.citizen.org/system/files/case_documents/rcep-data-exclusivity_0.pdf [https://perma.cc/N6JA-UNPB] ("The TRIPS drafters' refusal to adopt the NAFTA provision is one of several factors demonstrating their intention to provide for some level of data protection, but not data exclusivity, in TRIPS."). By contrast, Jacques Gorlin, who directed an ad hoc coalition of major U.S. corporations that pushed for the establishment of the TRIPS Agreement, has subscribed to a diametrically opposed view:

> United States negotiators agreed to drop the non-reliance language, because they viewed the phrase as no more than "belts and suspenders", that is, the accepted definition at the time of "protection against unfair commercial use" included non-reliance for a fixed period of time for new chemical entities and the second phrase was, therefore, not needed.

JACQUES J. GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL-RELATED PROVISIONS OF THE WTO TRIPS (INTELLECTUAL PROPERTY) AGREEMENT 48 (1999).

73. Reichman, *Undisclosed Clinical Trial Data*, *supra* note 72, at 142.

74. *See* VIKTOR MAYER-SCHÖNBERGER & KENNETH CUKIER, BIG DATA: A REVOLUTION THAT WILL TRANSFORM HOW WE LIVE, WORK AND THINK 19-31, 98-122 (2014) (noting the importance of large and comprehensive datasets in the big-data environment).

or commercialized in a foreign country."[75] Because the relevant test data are not submitted "as a condition of approving the marketing of" the regulated products,[76] Article 39.3 does not apply.[77]

The second, highly contentious area during the TRIPS negotiations, which the final text of Article 39.3 seems to have settled, relates to the requirement that WTO members introduce a data exclusivity regime. Commentators, myself included, have noted ad nauseum how data exclusivity is a TRIPS-plus demand that has gone beyond the WTO requirements.[78] Article 39.3 introduces two obligations: one "against unfair commercial use" and the other "against disclosure."[79] There is no additional obligation to provide exclusive rights in undisclosed test or other data for pharmaceutical and agrochemical products.

Thus far, developed countries and their pharmaceutical and agrochemical industries have taken the position that data exclusivity is necessary to provide effective protections for undisclosed test or other data. As Professor Correa observed:

> Despite the fact that Article 39.3 does not provide for the granting of exclusive rights, research-based industry and the governments of some developed countries have argued that investment made for developing test data can only be ensured if a minimum period (eg five

75. CORREA, *supra* note 10, at 376-77.

76. TRIPS Agreement, *supra* note 1, art. 39.3.

77. *See* CORREA, *supra* note 10, at 377 ("[I]f a Member country opts not to require those data, such as when the national authority relies on the marketing approval conferred in a foreign country, Article 39.3 does not apply.").

78. *See id*. at 391 ("The wording, context, and purpose of . . . [Article 39.3] does not allow to conclude that the required protection can only be implemented on the basis of an *exclusivity* period of protection."); COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 50 (2002) ("TRIPS does not require the imposition of data exclusivity, as such, on these test data, only protection against unfair commercial use."); WATAL, *supra* note 11, at 199 ("[I]n the TRIPS text there is no clear obligation not to rely on the test data for the second or subsequent applicants nor a fixed duration of market exclusivity, failing which the first registrant is assured reasonable compensation. This is a clear contrast to the corresponding provisions in NAFTA . . . ." (footnote omitted)); Fellmeth, *supra* note 49, at 455 ("[T]he rejection of the U.S. and [European Community] proposals proves that negotiators did not agree upon an unalloyed obligation to ensure data exclusivity under any of the proposed terms."); Yu, *The International Enclosure Movement*, *supra* note 5, at 868 (listing data exclusivity as a TRIPS-extra provision); Public Citizen, *supra* note 72, at 2 (noting that Article 39.3 "does not require 'data exclusivity' ").

79. TRIPS Agreement, *supra* note 1, art. 39.3; *see also* CORREA, *supra* note 10, at 391 ("[The] main purpose [of Article 39.3] is not to prevent the commercial use of [test] data by governments, but the use thereof by competitors."); WATAL, *supra* note 11, at 204 ("[A] reasonable interpretation [of Article 39.3 of the TRIPS Agreement] would be that the obligation on the authorities would be to keep the test data secret and to prohibit others from accessing this test data for unfair commercial use, such as sale to rival firms.").

> years for pharmaceuticals, ten years for agrochemicals) of exclusivity is granted.[80]

Likewise, the European Commission declared:

> In theory, any country maintaining an *effective* system to implement obligations under [Article] 39.3, even if different from non-reliance over time, would not be in breach of its TRIPs obligations, but we are not aware of many alternatives and it is clear that what the TRIPs-negotiators had in mind was data exclusivity over a certain period of time.[81]

Article 39.1 specifically requires WTO members to "ensur[e] effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967)."[82] When the obligations of Article 39.1 and 39.3 are linked together—as suggested by the italicized language advanced by the European Commission—one could make an argument that WTO members are required to introduce a data exclusivity regime to protect undisclosed test or other data so as to ensure effective protection in this area.[83]

Nevertheless, it is difficult to reconcile this argument with both the ordinary meaning of Article 39.3 and its negotiating history, including the highly influential 1990 Brussels draft. The claim of effective protection is greatly weakened by the TRIPS Agreement's failure to define the term "effective."[84] As if this ambiguity were not challenging enough, that term could also be interpreted in light of the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement[85]

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80. CORREA, *supra* note 10, at 374.

81. EUROPEAN COMM'N, *supra* note 32, at 21.

82. TRIPS Agreement, *supra* note 1, art. 39.1.

83. *See* EUROPEAN COMM'N, *supra* note 32, at 21 (noting the limited alternatives to provide "an *effective* system to implement obligations under [Article] 39.3" without introducing a data exclusivity regime); *see also* TRIPS Agreement, *supra* note 1, art. 39.1 (requiring WTO members to "ensur[e] effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention").

84. *See* Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in Post-WTO China*, 55 AM. U. L. REV. 901, 927 (2006) ("Although the TRIPs Agreement stipulates that each WTO member state needs to provide effective intellectual property enforcement, it does not define what constitutes 'effective' protection.").

85. TRIPS Agreement, *supra* note 1, arts. 7-8; *see also* J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 461 (2000) (suggesting that Articles 7 and 8 of the TRIPS Agreement may provide "a basis for seeking waivers to meet unforeseen conditions of hardship"); Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUS. L. REV. 979, 1018-46 (2009) (discussing the different ways Articles 7 and 8 can be used to facilitate a more flexible interpretation and implementation of the TRIPS Agreement).

and the technology transfer commitment provided in Article 66.[86] All in all, it is doubtful that the WTO requires its members to introduce a data exclusivity regime to offer effective protection under Article 39.3, unless the term "effective" is defined from the perspective of the pharmaceutical and agrochemical industries.

Another plausible, and more convincing, argument concerns the interpretation of the term "unfair commercial use." The validity of this argument likely varies according to one's perspective. Some WTO members, policymakers, and commentators take the position that reliance is per se unfair commercial use,[87] as such reliance allows the

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86. *See* TRIPS Agreement, *supra* note 1, art. 66 (requiring developed countries to provide incentives for their businesses and institutions to help "create a sound and viable technological base" in least developed countries by promoting and encouraging transfer of technology). As Paul Heald advocated:

> [P]rotection should further "public policy objectives . . . including developmental and technological objectives . . . [and enable the least developed members] to create a sound and viable technological base." It should also "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare." These objectives hardly dictate a narrow set of . . . options to developing countries. Moreover, one could interpret "effective" purely in terms of economic incentives: A member must provide a reward adequate to stimulate . . . successful research and development . . . .

Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN. L. REV. 249, 286 (2003) (footnotes omitted).

87. As the European Commission noted:

> [T]he only way to guarantee that no "unfair commercial use" within the meaning of Article 39.3 shall be made is to provide that regulatory authorities should not rely on these data for a reasonable period of time, the determination of what is a reasonable period of time being left to the discretion of the Members.

EUROPEAN COMM'N, *supra* note 32, at 19. Antony Taubman, who now directs the WTO Intellectual Property, Government Procurement and Competition Division, concurred:

> Competitors' commercial use of or benefit from regulatory data should be considered unfair and fit to be legally suppressed if it is likely systematically to deter submission and future production of such data: when the prospect of a competitor's immediate use of or benefit from the data is sufficient to render it irrational or unprofitable to generate the data initially, on the part of the originating firm, or when any competitor's use or benefit from test data that would, if systematically applied, deter future submissions.

Antony Taubman, *Unfair Competition and the Financing of Public-Knowledge Goods: The Problem of Test Data Protection*, 3 J. INTELL. PROP. L. & PRAC. 591, 606 (2008); *see also* DE CARVALHO, *supra* note 62, at 616 ("The whole idea of Article 39.3 is to prohibit parasitic behaviour or free riding. Any measures, such as reliance on bio-equivalence tests or other abridged procedures, that alleviate the subsequent registrant from obligations that have been imposed on the first registrant should be deemed as such."); Skillington & Solovy, *supra* note 37, at 33 ("[I]t is likely that a [WTO] panel would find a Member to be inconsistent with TRIPS Article 39.3 unless that Member provided some form of protection against unfair commercial use that differed from protection against disclosure.").

originator's competitors to acquire a commercial advantage. Professor Correa elaborated this line of argument as follows:

> [E]ven when neither the authority nor the competitor actually "use" the data without the originator's authorization (for instance, when the approval is given without any re-examination of the data) such unfair use might arise. In the complaint that the US made against Australia [via an investigation under Section 301 of the 1974 Trade Act], for instance, the US argued that relying on the innovator's data allowed free-riding by generic drug companies on the innovator company's investment in developing the test data and thus puts the innovator company at a competitive disadvantage . . . The US claims that Article 39 para (3) means that generic companies are not allowed to derive commercial benefit from the innovator's test data.[88]

"Commercial advantage" has indeed been a term that the United States has repeatedly pushed for inclusion in TRIPS-plus bilateral, regional, and plurilateral agreements. Article 23.1 of Anti-Counterfeiting Trade Agreement (ACTA),[89] for example, sought to increase the criminal enforcement obligation by redefining the term "commercial scale" as used in Article 61 of the TRIPS Agreement.[90] This provision declares: "acts carried out on a commercial scale include at least those carried out as commercial activities for direct or indirect economic or commercial advantage."[91] Article 18.77 of the TPP Agreement, which covers criminal procedures and penalties, further provides:

> In respect of wilful copyright or related rights piracy, "on a commercial scale" includes at least:
>
> (a) acts carried out for commercial advantage or financial gain; and

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88. CORREA, *supra* note 10, at 385; *see also* Fellmeth, *supra* note 49, at 456-57 (discussing the Section 301 investigation conducted by the United States Trade Representative).

89. Anti-Counterfeiting Trade Agreement, *opened for signature* May 1, 2011, 50 I.L.M. 243 (2011) [hereinafter ACTA].

90. *See* TRIPS Agreement, *supra* note 1, art. 61 ("Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale."). The term was particularly problematic in *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, when the WTO panel found that the United States failed to provide sufficient evidence to "demonstrate what constituted 'a commercial scale' in the specific situation of China's marketplace." Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights* ¶ 7.614, WTO Doc. WT/DS362/R (adopted Jan. 26, 2009). For the Author's discussions of the TRIPS criminal enforcement obligation in relation to this WTO dispute, see generally Peter K. Yu, *Shaping Chinese Criminal Enforcement Norms Through the TRIPS Agreement*, *in* CRIMINAL ENFORCEMENT OF INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH 286 (Christophe Geiger ed., 2012); Peter K. Yu, *TRIPS Enforcement and Developing Countries*, 26 AM. U. INT'L L. REV. 727, 731-34 (2011); Peter K. Yu, *The TRIPS Enforcement Dispute*, 89 NEB. L. REV. 1046, 1056-69, 1083-90 (2011).

91. ACTA, *supra* note 89, art. 23.1.

> (b) significant acts, not carried out for commercial advantage or financial gain, that have a substantial prejudicial impact on the interests of the copyright or related rights holder in relation to the marketplace.[92]

Apart from data reliance and data exclusivity—two highly divisive issues at the TRIPS negotiations—the contestations in the negotiation process and the various compromises struck between developed and developing countries have generated four unanswered questions. These questions have raised concerns among policymakers in developing countries and their supporting commentators and NGOs. The questions have also sparked the development of new norms or clarifications at the bilateral, regional, and plurilateral levels.[93] Because many of these questions relate to pharmaceutical products and implicate public health, the illustrations below will focus on these products, although one could easily make analogies to agrochemical products.

The first question concerns 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.[94] As Professor Correa observed:

> The issue of protection of data is especially relevant to off-patent products, since in cases where the product is patented, the patent holder can, in principle, exclude *any* competition during the lifetime of the patent. It is also of particular importance to many developing countries that had excluded patent protection for pharmaceuticals until recently. Because of such exclusion, in those countries there is still a large pool of pharmaceutical or agrochemical products that fall outside any patent rights. Data protection systems could, if they provided exclusivity, become a partial substitute for patent protection.[95]

To be sure, the duration of data exclusivity protection is usually shorter than the term of patent protection. In most circumstances, the protection of test or other data will expire before the end of the patent term. While the administrative delay caused by the regulatory approval process could shorten the effective marketing period of patented pharmaceutical products to about fourteen years,[96] that period is still

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92. TPP Agreement, *supra* note 12, art. 18.77 (footnotes omitted).

93. *See* discussion *infra* Part III.

94. *See* Ragavan, *Data Exclusivity*, *supra* note 41, at 252-53 (discussing the complications when the drug is in the public domain or when the granted patent for the drug has been subsequently invalidated).

95. CORREA, *supra* note 10, at 377.

96. As Kevin Outterson explained:

much longer than the usual five-year period of data exclusivity for these products.[97] Should a product's patent term be extended based on the Hatch-Waxman Act of 1984,[98] or its equivalents in TRIPS-plus bilateral, regional, and plurilateral agreements,[99] the product will enjoy a longer exclusive marketing period.

For pharmaceutical products that patent law no longer protects, however, data exclusivity law could provide substitutional protection. Although Article 39.3 of the TRIPS Agreement conditions protection on the existence of "new chemical entities," it does not require the relevant entities to meet the novelty standard commonly found in patent law.[100] Instead, the TRIPS Agreement provides WTO members with wide discretion to set their own standards.[101] For instance, policymakers and commentators in developed countries have widely considered

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> The exclusive marketing period is shorter than the 20-year patent term because several years pass from the patent date until the drug is approved for marketing. By the late 1990s, the U.S. pharmaceutical exclusive marketing period was approximately 14 years. There is some evidence that the period is longer for recent antibiotics. For the last two novel antibiotics approved by the [United States Food and Drug Administration (FDA)] (Zyvox/linezolid and Cubicin/daptomycin), the exclusive marketing period indicated by the FDA ORANGE BOOK is 14 to 21 years for Zyvox and 13 to 16 years for Cubicin.

Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 72 n.24 (2005) (citing CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 45-48 (1998)) (citations omitted).

97. *See* NAFTA, *supra* note 17, art. 1711.6 ("[A] reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them."); TPP Agreement, *supra* note 12, art. 18.50 (providing protection "for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party" (footnote omitted)).

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

99. *See, e.g.*, CAFTA–DR, *supra* note 24, art. 15.9.6; U.S.–Australia FTA, *supra* note 24, art. 17.9.8; U.S.–Singapore FTA, *supra* note 24, art. 17.9.8.

100. *See* CORREA, *supra* note 10, at 378 ("Presumably [the definition of 'new'] does not impose a patent standard of novelty, but nothing prevents a Member country from assimilating the concept of 'new' used in this Article to the one applied under patent law."); TRIPS RESOURCE BOOK, *supra* note 2, at 530 ("The Agreement does not define what should be meant by 'new'. Members may apply a concept similar to the one applied under patent law, or consider that a chemical entity is 'new' if there were no prior application for approval of the same drug."); Ragavan, *Data Exclusivity*, *supra* note 41, at 252-54 (discussing the distinction between the term "new chemical entities" and the "novelty" standard in patent law); Skillington & Solovy, *supra* note 37, at 27 ("There is no reason to assume that the term used in the context of determining patentability would be used identically in provisions for determining whether test data should be protected.").

101. *See* Yu, *The International Enclosure Movement*, *supra* note 5, at 869-70 (discussing the limitations, flexibilities, and public interest safeguards in the TRIPS Agreement). For commentaries emphasizing the flexibilities within the TRIPS Agreement, see generally CORREA, *supra* note 10; TRIPS RESOURCE BOOK, *supra* note 2.

the term "new chemical entities" to require only the lack of prior regulatory approval of the pharmaceutical products at issue.[102] The past decade has also seen the United States and other WTO members actively utilizing TRIPS-plus bilateral, regional, and plurilateral agreements to clarify the definition of newness. A case in point is Article 18.52 of the TPP Agreement, which states that "a *new pharmaceutical product* means a pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party."[103]

The second question pertains to the use of compulsory licenses—or, in TRIPS terms, "[the] use [of a patent] without authorization of the right holder."[104] Article 31 of the TRIPS Agreement delineates the complex conditions under which these licenses are to be issued for patented products.[105] Article 31*bis*, which recently entered into force,[106] also extends the compulsory licensing arrangement to countries with insufficient or no drug manufacturing capacity.[107] Unlike those two

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102. *See* CORREA, *supra* note 10, at 378 ("[A] chemical entity may be deemed 'new' if there were no prior application for approval of the same product in the Member where protection is sought."); GERVAIS, *supra* note 2, at 427 (noting that a "practical approach" could be to determine eligibility based on the fact that "a chemical entity is new in the WTO Member concerned, in the sense that it has not been previously submitted for regulatory approval of the type considered under this article"); Skillington & Solovy, *supra* note 37, at 25-28 (discussing the meaning of the term "new chemical entities"). As stated in the U.S. Food and Drug Administration regulations:

> If a drug product that contains a new chemical entity was approved . . . in [a new drug application] submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, no person may submit a 505(b)(2) application or [abbreviated new drug application] under section 505(j) of the Federal Food, Drug, and Cosmetic Act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved [new drug application], except that the 505(b)(2) application or [abbreviated new drug application] may be submitted after 4 years if it contains a certification of patent invalidity or noninfringement described in § 314.50(i)(1)(i)(A)(4) or § 314.94(a)(12)(i)(A)(4).

21 C.F.R. § 314.108(b)(2) (2018); *see also Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069962.htm [https://perma.cc/J4D3-G7NC] ("A new chemical entity means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the [Federal Food, Drug, and Cosmetic] Act.").

103. TPP Agreement, *supra* note 12, art. 18.52 (footnote omitted).

104. TRIPS Agreement, *supra* note 1, art. 31.

105. *See id.* (delineating these conditions).

106. The amendment was adopted in January 2017 after it had been opened for ratification for more than a decade. Press Release, World Trade Org., WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm [https://perma.cc/BUT5-XH36].

107. *See* General Council, *Amendment of the TRIPS Agreement*, WTO Doc. WT/L/641 (Dec. 8, 2005) (providing the text of Article 31*bis* of the TRIPS Agreement); *see also* Yu, *The*

provisions, however, Article 39.3 is not subject to the compulsory licensing arrangement provided in the TRIPS Agreement.[108] Indeed, if one goes back to the composite text Lars Anell, the chair of the TRIPS Negotiating Group,[109] advanced in his July 23, 1990 report, that text includes a distinct sentence declaring that "[t]here shall be no compulsory licensing of proprietary information."[110] The lack of coverage for compulsory licensing arrangements, therefore, has sparked an interesting debate concerning whether WTO members can utilize the test or other data submitted to regulatory authorities for the purposes of granting marketing approval of pharmaceutical products that have been, or are to be, issued under compulsory licenses.[111] Also debatable

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International Enclosure Movement, *supra* note 5, at 872-86 (tracing the development of Article 31*bis* of the TRIPS Agreement).

108. *Compare* TRIPS Agreement, *supra* note 1, art. 31, *with id.* art. 39.3.

109. *See* Lars Anell, *Foreword to the First Edition*, *in* GERVAIS, *supra* note 2, at ix (recounting the TRIPS negotiations from the vantage point of the chair of the TRIPS Negotiating Group); Lars Anell, *Keynote Speech at the TRIPS Symposium, 26 February 2015*, *in* THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 365 (Jayashree Watal & Antony Taubman eds., 2015) [hereinafter MAKING OF THE TRIPS AGREEMENT] (reminiscing about the TRIPS negotiations at the twentieth anniversary of the TRIPS Agreement).

110. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Chairman's Report to the GNG [General Negotiating Group]: Status of Work in the Negotiating Group*, at 23, GATT Doc. MTN.GNG/NG11/W/76 (July 23, 1990).

111. *Compare* ANGELINA SNODGRASS GODOY, OF MEDICINES AND MARKETS: INTELLECTUAL PROPERTY AND HUMAN RIGHTS IN THE FREE TRADE ERA 74 (2013) ("While Guatemala could choose to issue a compulsory license for [a drug], compulsory licenses are intended to loosen patents; their applicability to test data has not yet been tested anywhere in the world."), *with* CORREA, *supra* note 10, at 374 ("Under [the exceptions provided in Article 39.3], disclosure would be permissible . . . to allow a compulsory licensee to obtain a marketing approval, particularly when the licence is aimed at remedying anti-competitive practices or at satisfying public health needs."). *See also* Correa, *Protecting Test Data*, *supra* note 62, at 94 ("Since a compulsory licence or government use only permits the use of the patent, it may be necessary to waive the rights conferred under data exclusivity to obtain marketing approval of the relevant [pharmaceutical] product."); DE CARVALHO, *supra* note 62, at 649 ("The fact that Article 39.3 does not refer to compulsory licenses does not mean that it prohibits them. When TRIPS negotiators wished to prohibit compulsory licenses of intellectual property rights, they did so explicitly, as in Article 21."); Weissman, *supra* note 41, at 168-74 (discussing the compulsory licensing of pharmaceutical products and the development of a compulsory licensing system for registration data); Ellen F.M. 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10 J. PHARMACEUTICAL POL'Y & PRAC. 19, at 6 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490222/ [https://perma.cc/N3AZ-PV47] ("The right of governments to grant compulsory licences, including for public non-commercial use, is acknowledged in international law, including in TRIPS. Effective use of such licences requires a waiver of data exclusivity for the approval and marketing of licensed generic medicines."); Ragavan, *(Re)Newed Barrier*, *supra* note 62, at 1190 ("[T]he 'public interest' exception outlined in Article 39 can be used to create statutory exceptions in national legislations to the use of the data for approving a competitor's application to supply the market.").

is the possibility for waiving data exclusivity protection upon the issuance of such licenses.[112]

The third question regards the meaning of "undisclosed" information. Based on its ordinary meaning, the term does not include "information that is already public (eg, because it has been published in scientific journals or by another national health authority)."[113] Although this issue was not significantly important in the past, it will likely become more important in the future, especially with the growing push for the sharing of test or other data under open-access arrangements.[114] For example, the European Medicines Agency adopted a new publication policy that requires the agency to proactively publish test data that have been submitted to the agency after January 1, 2015 for initial marketing authorization.[115] The agency also publishes data that have been submitted after July 1, 2015 as part of an application for a new indication or line extension.[116] In addition, the U.N. Secretary-General's High-Level Panel on Access to Medicines called on governments to

> require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the [World Health Organization] Clinical Trials Registry Platform, clinicaltrials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.[117]

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112. *See* Correa, *Protecting Test Data*, *supra* note 62, at 94 (discussing the need "to waive the rights conferred under data exclusivity to obtain marketing approval of the relevant [pharmaceutical] product"); DE CARVALHO, *supra* note 62, at 650-51 (listing the provisions on compulsory licenses of test data in Brazilian and Saudi Arabian legislation); 't Hoen et al., *supra* note 111, at 4-5 (discussing data exclusivity waivers in Chilean, Colombian, and Malaysian legislation); Weissman, *supra* note 41, at 168-70 (discussing a data exclusivity waiver in cases of compulsory licensing of pharmaceutical products).

113. CORREA, *supra* note 10, at 378; *see also* Ragavan, *Data Exclusivity*, *supra* note 41, at 251 ("Article 39 leaves . . . room to determine the question of whether data undisclosed in one part of the world should be considered undisclosed in another part of the world.").

114. *See generally* COMM. ON STRATEGIES FOR RESPONSIBLE SHARING OF CLINICAL TRIAL DATA, INST. OF MED., SHARING CLINICAL TRIAL DATA: MAXIMIZING BENEFITS, MINIMIZING RISK (2015) (providing a detailed report outlining the benefits, risks, and challenges of sharing clinical trial data).

115. *See* European Medicines Agency, *European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*, EMA/240810/2013 (Oct. 2, 2014), http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf [https://perma.cc/Q5LG-EHW5]; *see also* Daria Kim, *Enabling Access to Clinical Trial Data: When Is Unfair Use Fair*, 14 CHI.-KENT J. INTELL. PROP. 521 (2015) (discussing whether the disclosure of clinical trial data by the European Medicines Agency for experimental use is consistent with Article 39.3 of the TRIPS Agreement).

116. *See* European Medicines Agency, *supra* note 115.

117. U.N. SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDS., PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 37 (2016).

Trudo Lemmens and Candice Telfer have also used the right to health to justify the disclosure of test or other data for pharmaceutical products.[118]

The final question involves the interplay,[119] and often the overlap,[120] between the different forms of intellectual property rights for pharmaceutical products. While Article 39.3 of the TRIPS Agreement offers only limited protection to undisclosed test and other data, TRIPS-plus bilateral, regional, and plurilateral agreements have called for not only market or data exclusivity for test or other data for pharmaceutical and agrochemical products but also for a considerable increase in patent standards, extension of the patent term due to regulatory delay, protections for new uses (or second indications) of known chemical compounds, linkage of drug registration to patent status, and strengthening of enforcement relating to the seizure of in-transit drugs.[121] Given the increasing demands for these new protections, policymakers and commenters are understandably concerned that the

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118. *See* Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 AM. J.L. & MED. 63, 66 (2012) ("[A]ccess to information about clinical trials, which is a crucial tool for drug and medical device development, ought to be recognized as a fundamental component of the right to health."). For the Author's earlier discussions of the interplay between intellectual property and human rights, see generally Peter K. Yu, *Digital Copyright Enforcement Measures and Their Human Rights Threats*, *in* RESEARCH HANDBOOK ON HUMAN RIGHTS AND INTELLECTUAL PROPERTY 455 (Christophe Geiger ed., 2015); Peter K. Yu, *Intellectual Property, Human Rights and Methodological Reflections*, *in* APPROACHES AND METHODOLOGIES IN INTELLECTUAL PROPERTY RESEARCH (Irene Calboli & Lillà Montagnani eds., forthcoming 2019); Peter K. Yu, *The Anatomy of the Human Rights Framework for Intellectual Property*, 69 SMU L. REV. 37 (2016); Peter K. Yu, *Intellectual Property and Human Rights 2.0*, 53 U. RICH. L. REV. 1375 (2019); Peter K. Yu, *Intellectual Property and Human Rights in the Nonmultilateral Era*, 64 FLA. L. REV. 1045 (2012) [hereinafter Yu, *Nonmultilateral Era*]; Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039 (2007) [hereinafter Yu, *Reconceptualizing Intellectual Property Interests*]; Peter K. Yu, *Ten Common Questions About Intellectual Property and Human Rights*, 23 GA. ST. U. L. REV. 709 (2007).

119. *See* Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419, 476-79 (2012) (documenting the interplay between the patent term and the terms of regulatory exclusivities).

120. *See id.* at 462 (noting that concurrent protection in biologicals "leads to a waste of societal resources" and "gives rise to unnecessary and avoidable risks of abuse" (capitalization omitted)); Srividhya Ragavan, *The Drug Debate: Data Exclusivity Is the New Way to Delay Generics*, 50 CONN. L. REV. ONLINE 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."). For discussions of overlapping rights, see generally ESTELLE DERCLAYE & MATTHIAS LEISTNER, INTELLECTUAL PROPERTY OVERLAPS: A EUROPEAN PERSPECTIVE (2011); OVERLAPPING INTELLECTUAL PROPERTY RIGHTS 189 (Neil Wilkof & Shamnad Basheer eds., 2012); Mark A. Lemley, *Dealing with Overlapping Copyrights on the Internet*, 22 U. DAYTON L. REV. 547 (1997).

121. *See* Yu, *The International Enclosure Movement*, *supra* note 5, at 867-69 (discussing the different types of TRIPS-plus standards). The linkage of drug registration to patent status is often discussed alongside the protection of test and other data, due in large part to the pharmaceutical industry's concurrent demands. For discussions of this linkage, see generally

simultaneous introduction or adjustment of multiple intellectual property standards would lead to overprotection.[122] Some commentators have also explored the substitutability of the different forms of intellectual property rights.[123] After all, if the protections for undisclosed test or other data have already been increased to provide additional incentives, a country may not need to simultaneously extend the patent term.[124]

C. Conflict

To illustrate the significant disagreement between developed and developing countries at the TRIPS negotiations and the ramifications of the continued contestations over the appropriate international minimum standards in this area, this Section recounts the WTO dispute between Argentina and the United States over the lack of adequate

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Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303 (2008); Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 88-91 (2004).

122. *See* Yu, *Data Exclusivities*, *supra* note 11, at 26 ("[M]any developing countries are concerned about the impact of the changing standards not only for a single form of intellectual property right, such as the protection of clinical trial data, but also for a combination of multiple forms of intellectual property rights.").

123. *See generally* Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399 (2013) (proposing a nonpatent exclusivity system administered by the Food and Drug Administration that offers the incentives traditionally provided by the patent system); Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53 (2016) (discussing the rise of "regulatory property" as a new form of intellectual property); Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357 (2019) (proposing an extension of the duration of data exclusivity protection in exchange for not applying for a patent or allowing the patent to lapse); Heled, *supra* note 119 (questioning the need for and purpose of having patent rights and statutory exclusivities in biologics); John R. Thomas, *The End of "Patent Medicines"?: Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39 (2015) (exploring the implications of the pharmaceutical industry's growing preference for regulatory exclusivities to patent protection).

124. As I noted in an earlier article:

> While pharmaceutical manufacturers may still need incentives to obtain marketing approval for their products, most of the marketing costs are already included in the total costs that are used to justify stronger patent protection. Unless the regulatory authorities in foreign countries require different clinical trials during the approval process, additional incentives seem to be unnecessary. Indeed, if 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.

Yu, *Political Economy*, *supra* note 57, at 784-85; *see also* Heled, *supra* note 119, at 461-64 (discussing the undesirable ramifications of providing concurrent protection to biologics using both patent rights and statutory exclusivities); Yu, *The International Enclosure Movement*, *supra* note 5, at 895 ("If additional incentives are provided by the data exclusivity regime, one has to wonder whether patent protection should be weakened proportionally to reflect the additional incentives.").

protection for test and other data for pharmaceutical and agrochemical products. In the twenty-five years of existence of the WTO dispute settlement process, this dispute is the only one involving Article 39.3 of the TRIPS Agreement.

On May 6, 1999, the United States filed a complaint against Argentina before the WTO Dispute Settlement Body.[125] This complaint was initiated following the Clinton Administration's suspension of half of Argentina's trade benefits under the U.S. Generalized System of Preferences in April 1997.[126] In addition to alleging inadequate protection of pharmaceutical products under the patent system or through exclusive marketing rights,[127] the WTO complaint claimed that Argentina had violated the TRIPS Agreement by repealing a regulation that had provided ten years of protection for undisclosed test or other data for agrochemical products.[128] As the complaint declared:

> Prior to August 1998, the Government of Argentina provided a ten-year term of protection against unfair commercial use for undisclosed test data or other data submitted to Argentine regulatory authorities in support of applications for marketing approval for agricultural chemical products. Since the issuance in 1998 of Regulation 440/98, which *inter alia* revoked earlier regulations, Argentina has provided no effective protection for such data against unfair commercial use. As a result, Argentina's legal regime appears to be inconsistent with the obligation in Article 65.5 of the TRIPS Agreement in that changes to its laws, regulations or practice during the transitional period have resulted in a lesser degree of consistency with the provisions of Article 39.3 of the TRIPS Agreement.[129]

On May 30, 2000, slightly more than a year later, the United States filed a second complaint against Argentina alleging a lack of adequate

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125. *WTO Complaint 1*, *supra* note 23.

126. *See* Fellmeth, *supra* note 49, at 457 ("In 1997, . . . the Clinton administration withdrew Argentina's preferential tariff rates granted under the Generalized System of Preferences, reducing Argentinean imports into the United States by an estimated $260 million."); *see also* Dan Molinski, *Argentina Protests Tariff Action*, J. COM., Apr. 17, 1997, at 3A (reporting the suspension).

127. Article 70.9 of the TRIPS Agreement provides:

> Where a product is the subject of a patent application in a Member in accordance with [Article 70.8(a)], exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

TRIPS Agreement, *supra* note 1, art. 70.9.

128. *WTO Complaint 1*, *supra* note 23, at 2.

129. *Id.*

protection of undisclosed test or other data for pharmaceutical and agrochemical products.[130] In addition to select patent provisions in Argentina, the United States challenged Argentine laws and regulations that covered such protection—namely, Law 24.766, Regulation 440/98, and other related measures.[131] As the complaint stated, the United States believed that "Argentina [had] fail[ed] to protect against unfair commercial use of undisclosed test or other data, submitted as a requirement for market approval of pharmaceutical or agricultural chemical products."[132]

From a standpoint of TRIPS interpretation, this complaint can be highly important, as it could result in the issuance of a WTO panel report, and, perhaps, even a follow-up Appellate Body report.[133] Article 64 of the TRIPS Agreement specifically requires WTO members to use the WTO dispute settlement process to settle disputes arising under the Agreement.[134] Notwithstanding the potential for a WTO panel to weigh in on the international obligations provided by Article 39.3 of the TRIPS Agreement, Argentina and the United States settled the dispute on May 31, 2002, before the complainant's request for the establishment of a WTO panel.[135]

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130. *WTO Complaint 2*, *supra* note 23.

131. *Id.* at 1; *see also* Law No. 24766, Dec. 17, 1996, https://wipolex.wipo.int/en/legislation/details/103 [https://perma.cc/P2LD-5BKW] (Arg.); Resolution No. 440/98, July 22, 1998, https://wipolex.wipo.int/en/legislation/details/106 [https://perma.cc/9T7B-RQK9] (Arg.).

132. *WTO Complaint 2*, *supra* note 23, at 1.

133. Article 3.2 of the Dispute Settlement Understanding provides:

> The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the [Dispute Settlement Body] cannot add to or diminish the rights and obligations provided in the covered agreements.

Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

134. TRIPS Agreement, *supra* note 1, art. 64.

135. Notification of Mutually Agreed Solution, *Argentina—Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals* and *Argentina—Certain Measures on the Protection of Patents and Test Data*, WTO Docs. WT/DS171/3, WT/DS196/4 (June 20, 2002) [hereinafter *WTO Settlement Notification*]; *see also* CORREA, *supra* note 10, at 389 n.54 (noting that the case "was settled without any change in Argentina's legislation with regard to data protection"). Professor Correa described the aftermath of this dispute:

> Argentina did not accept the US claim that exclusive rights should be granted for test data and maintained its law unchanged. No further action in the framework of the WTO has been taken by [the] US against Argentina, or any other country that does not recognize data exclusivity. However, the US Office of the Trade Representative (USTR) has listed, under the Special Section 301 of the

The mutually agreed upon solutions that the parties transmitted to the WTO Dispute Settlement Body focused primarily on the resolution of patent disputes.[136] Among the disputes resolved were those concerning compulsory licenses, exclusive marketing rights, import restrictions, product-by-process patents, burden of proof in patent infringement cases, preliminary injunctions, patentability of micro-organisms and other subject matter, and transitional patents.[137] However, no solution was offered in relation to the United States' complaint about Argentina's inadequate protection of undisclosed test and other data for pharmaceutical and agrochemical products. As the notification of settlement stated:

> The Governments of the United States and Argentina have expressed their respective points of view on the provisions of Article 39.3 of the TRIPS Agreement, and have agreed that differences in interpretations shall be solved under the [Dispute Settlement Understanding] rules. The Parties will continue consultations to assess the progress of the legislative process of approval of items 4, 5 and 6 of this notification [which cover product-by-process patents, burden of proof in patent infringement cases, and preliminary injunctions], and in the light of this assessment, the United States may decide to continue consultations or request the establishment of a panel related to Article 39.3 of the TRIPS Agreement.
>
> In addition, the Parties agree that should the Dispute Settlement Body adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data submitted for marketing approval according to Article 39.3 of the TRIPS Agreement, and should Argentinean law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings.[138]

Although the United States notified the WTO that it might continue consultations with Argentina or make a later request for the establishment of a panel,[139] neither actions took place.[140] As a result, the official

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Trade Act, a large number of countries that, according to the USTR, do not confer adequate (that is, exclusive) protection for test data.

Correa, *Protecting Test Data*, *supra* note 62, at 85.

136. *WTO Settlement Notification*, *supra* note 135.

137. *Id.* at 2-5.

138. *Id.* at 6.

139. *Id.*

140. As Kenneth Shadlen observed: "The reason why the US dropped the case is not known with certainty, but it appears to be because it feared that a WTO ruling would favor Argentina's interpretation of TRIPS, and the precedent set by losing in the multilateral body

interpretation of Article 39.3 has remained as contested today as the time of the United States' complaint against Argentina.

III. TRIPS-PLUS DEVELOPMENTS

Immediately after the adoption of the TRIPS Agreement, developed countries and their intellectual property industries extolled its many achievements. As Jacques Gorlin—the director of an ad hoc coalition of major U.S. corporations that pushed for the establishment of the TRIPS Agreement[141]—proudly observed, his Intellectual Property Committee got ninety-five percent of what it wanted.[142] Notwithstanding this success, intellectual property rights have not been protected and enforced to the satisfaction of U.S. intellectual property industries—and likely, their counterparts in other developed countries.[143] Conscious of this continuous lack of effective protection and enforcement of intellectual property rights, the United States and the European Union actively pushed for the negotiation of TRIPS-plus bilateral and regional trade agreements.

Since the mid-2000s, the United States established free trade agreements "with Australia, Bahrain, Chile, Colombia, Israel, Jordan, Morocco, Oman, Panama, Peru, Singapore, and South Korea."[144] In May 2004, the United States also became a party to the Dominican Republic–Central America Free Trade Agreement, along with Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras,

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would undermine efforts to secure data exclusivity in other countries." SHADLEN, *supra* note 23, at 152-53 n.17.

141. Formed in March 1986, the Intellectual Property Committee brought together top corporate executives from about a dozen United States–based multinational firms. In addition to coordinating industry positions on intellectual property policies with the U.S. government, the Committee was instrumental in "forging an industry consensus with its Japanese and European industry counterparts [Keidanren and UNICE (Union of Industrial and Employers' Confederations of Europe), respectively], who agreed to work on [a trade-based approach to protecting intellectual property] and pledged to present these views to their respective governments in time for the launching of the Uruguay Round." SELL, *supra* note 22, at 106; *see also id.* at 96-120 (discussing the role of the Intellectual Property Committee in pushing for the adoption of high intellectual property standards in the TRIPS Agreement).

142. *Id.* at 115 (citing interview with Jacques Gorlin).

143. *See* Peter K. Yu, *TRIPS and Its Achilles' Heel*, 18 J. INTELL. PROP. L. 479, 505 (2011) [hereinafter Yu, *Achilles' Heel*] (noting the developed countries' deep dissatisfaction with the continuous piracy and counterfeiting problems in developing countries and explaining why the former did not push for stronger international intellectual property enforcement norms until the mid-2000s).

144. Peter K. Yu, *The Non-multilateral Approach to International Intellectual Property Normsetting*, *in* INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH 83, 86 (Daniel J. Gervais ed., 2015) [hereinafter Yu, *Non-multilateral Approach*].

and Nicaragua.[145] Meanwhile, the European Union established economic partnership or free trade agreements "with Chile, Colombia, Mexico, Peru, South Africa, South Korea and members of the Caribbean Forum (CARIFORUM)."[146]

All of these nonmultilateral agreements include chapters dedicated to the protection and enforcement of intellectual property rights. The primary objective of these chapters is to set high standards for intellectual property protection and enforcement that go beyond the TRIPS requirements.[147] To a large extent, the justification for TRIPS-plus intellectual property chapters is not that different from the justification for the TRIPS Agreement in the late 1980s and early 1990s.[148] During the Uruguay Round negotiations, developing countries were repeatedly "told to overlook the distasteful aspects of introducing or increasing intellectual property protection and enforcement in exchange for longer-term economic health."[149]

Out of all the new intellectual property standards introduced through TRIPS-plus bilateral, regional, and plurilateral agreements, one set of standards that has garnered considerable policy, scholarly, and media attention concerns the protection of undisclosed test or other data for pharmaceutical and agrochemical products. Because all of these agreements have introduced similar language, this Part focuses on the three latest regional or plurilateral agreements: the TPP Agreement, the proposed RCEP Agreement, and the recently signed USMCA. While such a focus does not show the gradual upward ratchet of international intellectual property standards, a close

145. CAFTA–DR, *supra* note 24, art. 15.1.3(a); *see also* Carlos M. Correa, *A Model Law for the Protection of Undisclosed Data*, *in* INTELLECTUAL PROPERTY AND SUSTAINABLE DEVELOPMENT: DEVELOPMENT AGENDAS IN A CHANGING WORLD 370 (Ricardo Meléndez-Ortiz & Pedro Roffe eds., 2009) (discussing the protection of undisclosed test or other data for pharmaceutical and agrochemical products in relation to the Dominican Republic-Central America Free Trade Agreement).

146. Yu, *Non-multilateral Approach*, *supra* note 144, at 86.

147. *See* Press Release, Office of the U.S. Trade Representative, USTR Begins TPP Talks in Australia (Mar. 15, 2010) [hereinafter TPP Launch Press Release], https://ustr.gov/about-us/policy-offices/press-office/press-releases/2010/march/ustr-begins-tpp-talks-australia [https://perma.cc/S6KY-C476] ("Trans-Pacific Partnership negotiations offer a unique opportunity to shape a high-standard, broad-based regional pact. . . . Our . . . negotiators will be working to set a new standard for 21st century trade pacts."); *see also* Yu, *Thinking About TPP*, *supra* note 12, at 110-15 (discussing the TPP Agreement as a TRIPS-plus intellectual property agreement).

148. *See supra* authorities cited in note 22.

149. Daniel J. Gervais, *The TRIPS Agreement and the Doha Round: History and Impact on Economic Development*, *in* 4 INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE 23, 43 (Peter K. Yu ed., 2007); *see also* Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13 UCLA PAC. BASIN L.J. 166 (1994) (arguing that developing countries agreed to stronger intellectual property protection during the TRIPS negotiations because they found such protection to be in their self-interest).

analysis of these agreements reveals the latest contestations over the international minimum standards for protecting undisclosed test or other data for pharmaceutical and agrochemical products, as well as the active—and, for some, highly problematic[150]—developments outside the WTO.

A. TPP

The negotiations for the TPP Agreement began in earnest in March 2010.[151] Building on the Trans-Pacific Strategic Economic Partnership Agreement[152]—a quadrilateral agreement involving Brunei Darussalam, Chile, New Zealand, and Singapore, known widely as the P4 or the Pacific 4[153]—the TPP negotiations involved Australia, Canada, Japan, Malaysia, Mexico, Peru, Vietnam, the United States, and the P4 members. After nearly six years of negotiations, the TPP Agreement was finally signed in Auckland, New Zealand in February 2016.[154] Included in this agreement is a chapter on intellectual property rights.[155] Out of the eighty-three provisions in that chapter, three relate to the protection of undisclosed test and other data: Article 18.47 (for agrochemical products),[156] Article 18.50 (for pharmaceutical products),[157] and Article 18.51 (for biologics).[158]

Unlike Article 39.3 of the TRIPS Agreement, which protects against "unfair commercial use" and disclosure,[159] Article 18.47 of the TPP Agreement requires parties to establish a market exclusivity regime.[160] Although commentators often describe this regime as "data exclusivity," the term "market exclusivity" is more accurate because the TPP

150. *See* discussion *infra* text accompanying notes 228-230.

151. TPP Launch Press Release, *supra* note 147.

152. Trans-Pacific Strategic Economic Partnership Agreement, Brunei–Chile–N.Z.–Sing., Aug, 2, 2005, https://www.mfat.govt.nz/assets/FTAs-agreements-in-force/P4/Full-text-of-P4-agreement.pdf [https://perma.cc/6DBA-YFPC].

153. Meredith Kolsky Lewis, *Expanding the P-4 Trade Agreement into a Broader Trans-Pacific Partnership: Implications, Risks and Opportunities*, 4 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 401, 403-04 (2009).

154. Press Release, Office of the U.S. Trade Representative, Trans-Pacific Partnership Ministers' Statement (Feb. 4, 2016), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/February/TPP-Ministers-Statement [https://perma.cc/WZ3P-Z8Q8].

155. TPP Agreement, *supra* note 12, ch. 18; *see also* Emily Michiko Morris, *Much Ado About the TPP's Effect on Pharmaceuticals*, 20 SMU SCI. & TECH. L. REV. 135 (2017) (discussing the TPP's potential impact on drug prices and access to healthcare).

156. TPP Agreement, *supra* note 12, art. 18.47.

157. *Id.* art. 18.50.

158. *Id.* art. 18.51.

159. TRIPS Agreement, *supra* note 1, art. 39.3.

160. TPP Agreement, *supra* note 12, art. 18.47.

regime merely prevents the marketing of a new pharmaceutical or agrochemical product based on the utilization of, or reliance on, previously submitted test or other data.[161] However, the regime does not grant exclusive rights in the data, nor does it prevent the utilization of, or reliance on, such data during the exclusivity term. As I noted in an earlier article:

> The distinction between market exclusivity and data exclusivity is noteworthy. . . . By the time [the exclusivity] term is over, follow-on . . . developers [of pharmaceutical and agrochemical products] will still have to spend considerable time pushing their products through the regulatory process to secure marketing approval. Thus, a data exclusivity regime will generally provide a longer period of protection than a market exclusivity regime.[162]

For agrochemical products, the TPP Agreement grants protection "for at least 10 years from the date of marketing approval of the new . . . product in the territory of the Party."[163] For pharmaceutical products, by contrast, the protection lasts "for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party."[164] For the latter, Article 18.50.2 offers additional protection to new clinical information or molecular variations.[165] Under this provision, TPP partners could 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

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161. *See* Yu, *Data Exclusivities*, *supra* note 11, at 27 (expressing preference for the term "market exclusivity" to the term "data exclusivity"). As Erika Lietzan observed:

> 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. Others use "data exclusivity" to refer to statutory provisions relating to either approval or submission of *abbreviated applications*, on the theory that these applications rely on the data submitted in earlier applications.

Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 103 (2016).

162. Yu, *Data Exclusivities*, *supra* note 11, at 27. As a document released by Public Citizen explained:

> If a drug truly had five years of data exclusivity, the marketing authority would not be able to consider a generic application for five years, which would, in turn, provide the innovator another one to three years of market monopoly after the data exclusivity period expires before a generic could be approved and enter the market. This is because it takes that long for the marketing authority to analyze the generic's application and grant it marketing approval.

Public Citizen, *supra* note 72, at 3.

163. TPP Agreement, *supra* note 12, art. 18.47.1 (footnote omitted).

164. *Id.* art. 18.50.1(a) (footnote omitted).

165. *Id.* art. 18.50.2(a).

formulation or new method of administration."[166] In the alternative, they could afford 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."[167]

Article 18.51, which covers biologics, was among the most controversial provisions toward the end of the TPP negotiations.[168] Similar to the provision on pharmaceutical products—that is, chemical drugs, not biological drugs—this provision requires the establishment of a market exclusivity regime.[169] Although the United States initially pushed for twelve years of protection for biologics,[170] the TPP negotiating parties ended up with "at least eight years from the date of first marketing approval."[171] That compromise term would last longer than the market exclusivity period for chemical drugs, but it would be shorter than the period for agrochemical products.[172] To address the strong disagreement among the TPP negotiating parties, Article 18.51 allows each party to decide whether to offer market exclusivity for at least eight years or to offer such exclusivity for at least five years and then supplement such exclusivity with "other measures" for the remaining years.[173]

Finally, the TPP negotiating parties were conscious of the different levels of development among the like-minded parties, and that some

166. *Id.*

167. *Id.* art. 18.50.2(b) (footnote omitted).

168. *See* Frederick M. Abbott, *The Evolution of Public Health Provisions in Preferential Trade and Investment Agreements of the United States*, *in* CURRENT ALLIANCES IN INTERNATIONAL INTELLECTUAL PROPERTY LAWMAKING: THE EMERGENCE AND IMPACT OF MEGA-REGIONALS 45, 55 (Pedro Roffe & Xavier Seuba eds., 2017) [hereinafter Abbott, *Evolution of Public Health Provisions*] (noting that "negotiation of the duration of the biologics exclusivity period was perhaps the most controversial part of the TPP negotiations"); Burcu Kilic & Courtney Pine, *Decision Time on Biologics Exclusivity: Eight Years Is No Compromise*, INTELL. PROP. WATCH (July 27, 2015), http://www.ip-watch.org/2015/07/27/decision-time-on-biologics-exclusivity-eight-years-is-no-compromise/ [https://perma.cc/N265-MEY8] ("As the Trans-Pacific Partnership . . . negotiations approach their endgame, biologics exclusivity is still considered 'one of the most difficult outstanding issues in the negotiation.' ").

169. *See* TPP Agreement, *supra* note 12, art. 18.51.1 (providing "effective market protection" to biologics).

170. *See* Kilic & Pine, *supra* note 168 ("In late 2013, the United States Trade Representative . . . proposed 12 years of exclusivity (which functions as marketing exclusivity rather than data exclusivity) for biologics in the TPP, even though this contradicts and is mutually exclusive with the Administration's domestic policy proposals."); *see also* 42 U.S.C. § 262(k)(7)(A) (2018) (providing twelve years of protection for biologics).

171. TPP Agreement, *supra* note 12, art. 18.51.1(a).

172. *Compare id.*, *with id.* arts. 18.47.1, 18.50.1(a).

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

parties might "require changes to their law" to comply with the finalized agreement.[174] The TPP intellectual property chapter therefore includes transition arrangements in its final provisions.[175] Specifically, Article 18.83 sets out the transition periods for agrochemical, pharmaceutical, and biological products for Brunei Darussalam, Malaysia, Mexico, Peru, and Vietnam.[176] The Agreement also contains annexes clarifying the obligations of Chile, Malaysia, and Peru regarding the protection of undisclosed test or other data for pharmaceutical and biological products.[177]

Although the United States signed the TPP Agreement under the Obama Administration, President Donald Trump directed the United States Trade Representative to "withdraw the United States as a signatory to the [TPP and] . . . from TPP negotiations."[178] In the wake of this withdrawal, the eleven remaining TPP partners established the CPTPP,[179] which they signed in Santiago, Chile, on March 8, 2018.[180] With ratifications by Mexico, Japan, Singapore, New Zealand, Canada, Australia, and Vietnam—more than the six parties needed to bring the agreement into force—the CPTPP entered into force on December 30, 2018.[181]

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174. *Id.* art. 18.83.1 n.160.

175. *See id.* art. 18.83.

176. *See id.* art. 18.83.4(a)(iii)-(v) (providing to Brunei Darussalam a eighteen-month transition period for agrochemical products and a four-year transition period for both pharmaceutical and biological products); *id.* art. 18.83.4(b)(vii) (providing to Malaysia a five-year transition period for only biological products); *id.* art. 18.83.4(c)(ii), (iv), (v) (providing to Mexico a five-year transition period for agrochemical, pharmaceutical, and biological products); *id.* art. 18.83.4(e) (providing to Peru a five-year transition period for pharmaceutical products and a ten-year transition period for biological products); *id.* art. 18.83.4(f)(viii), (x), (xi) (providing to Vietnam a five-year transition period for agrochemical products and a ten-year transition period for both pharmaceutical and biological products).

177. *See id.* Annex 18-B.1 ("Nothing in Article 18.50.1 or Article 18.50.2 (Protection of Undisclosed Test or Other Data) or Article 18.51 (Biologics) prevents Chile from maintaining or applying the provisions of Article 91 of Chile's Law No. 19.039 on Industrial Property . . . ."); *id.* Annex 18-C.1 ("Malaysia may . . . require an applicant to commence the process of obtaining marketing approval for pharmaceutical products covered under [Articles 18.50 and 18.51] within 18 months from the date that the product is first granted marketing approval in any country."); *id.* Annex 18-D, pt. 2 (clarifying Peru's obligations in relation to Articles 18.50 and 18.51 of the TPP Agreement).

178. Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement, 82 Fed. Reg. 8497 (Jan. 23, 2017).

179. CPTPP, *supra* note 13.

180. *See* Dave Sherwood & Felipe Iturrieta, *Asia-Pacific Nations Sign Sweeping Trade Deal Without U.S.*, REUTERS (Mar. 8, 2018), https://www.reuters.com/article/us-trade-tpp/asia-pacific-nations-sign-sweeping-trade-deal-without-u-s-idUSKCN1GK0JM?il=0 [https://perma.cc/FMZ9-KA5D] (reporting the signing of the CPTPP).

181. *See* Ankit Panda, *The CPTPP Trade Agreement Will Enter into Force*, DIPLOMAT (Nov. 1, 2018), https://thediplomat.com/2018/11/the-cptpp-trade-agreement-will-enter-into-force-on-december-30/ [https://perma.cc/4AAR-FNUX] (reporting Australia's ratification of the CPTPP); Khanh Vu, *Vietnam Becomes Seventh Country to Ratify Trans-Pacific Trade*

Although the CPTPP retains Article 18.47 concerning the protection of undisclosed test or other data for agrochemical products, the Agreement suspended Articles 18.50 (for pharmaceutical products) and 18.51 (for biologics).[182] As stated in Article 2 of the CPTPP, which references the agreement's Annex, "[u]pon the date of entry into force of this Agreement, the Parties shall suspend the application of [these two] provisions . . . until the Parties agree to end suspension of one or more of these provisions."[183] In sum, even though the TPP partners have arguably achieved consensus, the withdrawal of the United States and the eventual establishment of the CPTPP reveal the continuous contestations over the international minimum standards for the protection of undisclosed test or other data for pharmaceutical and biological products.

B. RCEP

The negotiations for the RCEP were launched in November 2012 between ASEAN and its six trading neighbors (Australia, China, India, Japan, New Zealand, and South Korea).[184] Building on the past trade and nontrade discussions under the ASEAN+6 Framework, the negotiations aimed to create an area that "account[s] for almost half of the world's population, over 30 per cent of global [gross domestic product] and over a quarter of world exports."[185] These figures compare favorably with those relating to the TPP, which covers "40% of global [gross domestic product] and some 30% of worldwide trade in both goods and services."[186]

Thus far, it remains unclear whether the finalized RCEP Agreement will contain an intellectual property chapter. Nevertheless, a key negotiating document, the *Guiding Principles and Objectives for Negotiating the Regional Comprehensive Economic Partnership*, specifically mentions "[t]he text on intellectual property in the RCEP." [187]

Pact, REUTERS (Nov. 12, 2019), https://www.reuters.com/article/us-trade-tpp/vietnam-becomes-seventh-country-to-ratify-trans-pacific-trade-pact-idUSKCN1NH0VF [https://perma.cc/37GM-NVMW] (reporting Vietnam's ratification of the CPTPP).

182. *See* CPTPP, *supra* note 13, art. 2, Annex (suspending articles 18.50 and 18.51 of the TPP Agreement).

183. *Id.* art. 2.

184. Joint Declaration, *supra* note 14.

185. *Regional Comprehensive Economic Partnership*, AUSTL. GOV'T DEP'T FOREIGN AFF. & TRADE, http://dfat.gov.au/trade/agreements/rcep/pages/regional-comprehensive-economic-partnership.aspx [https://perma.cc/6BE7-NMNS].

186. David A. Gantz, *The TPP and RCEP: Mega-Trade Agreements for the Pacific Rim*, 33 ARIZ. J. INT'L & COMP. L. 57, 59 (2016).

187. ASEAN Plus Six, Guiding Principles and Objectives for Negotiating the Regional Comprehensive Economic Partnership pt. V (Aug. 30, 2012), https://dfat.gov.au/trade/agreements/negotiations/rcep/Documents/guiding-principles-rcep.pdf [https://perma.cc/TLP5-BZST].

Knowledge Ecology International, an NGO active in the health and intellectual property areas, has also leaked an early draft of the RCEP intellectual property chapter.[188] Although that draft was dated October 15, 2015 and the negotiating text has most certainly evolved following the United States' withdrawal from the TPP and the CPTPP's suspension of select TPP provisions, it is highly unlikely that the RCEP negotiating parties will abandon their plan to include an intellectual property chapter.[189]

As revealed by the leaked October 2015 text, the patent section of the draft RCEP intellectual property chapter includes a TRIPS-plus provision requiring the introduction of a data exclusivity regime to prevent the reliance on, or referral to, test or other data submitted for marketing approval of pharmaceutical products.[190] Proposed by Japan and South Korea and opposed by ASEAN, Australia, China, India, and New Zealand, the draft provision reads:

> Each Party shall prevent applicants for marketing approval for pharmaceutical products which utilize new chemical entities from relying on or from referring to test or other data submitted to its competent authority by the first applicant for a certain period of time counted from the date of approval of that application. As of the date of entry into force of this Agreement, such period of time is stipulated as being no less than five years by the relevant laws of each Party.[191]

Going beyond the TRIPS Agreement, the draft RCEP provision creates new obligations regarding both data reliance and data referral.[192] While Article 1711.6 of NAFTA prohibits data reliance, it does not include any language on data referral.[193] The draft RCEP provision also adopts the "no less than five years" duration found in NAFTA[194] and the now-rejected bracketed text in the 1990 Brussels draft of the

188. Regional Comprehensive Economic Partnership Intellectual Property Chapter (Oct. 15 draft) [hereinafter October 15 Draft], http://keionline.org/sites/default/files/RCEP-IP-Chapter-15October2015.docx [https://perma.cc/W32W-PMNB]; *see also* James Love, *2015 Oct 15 Version: RCEP IP Chapter*, KNOWLEDGE ECOLOGY INT'L (Apr. 19, 2016), http://keionline.org/node/2472 [https://perma.cc/C52G-PXSW] (providing the leaked October 15, 2015 text of the proposed RCEP intellectual property chapter).

189. *See* Yu, *RCEP and Trans-Pacific Norms*, *supra* note 15, at 722 (explaining why the RCEP Agreement will most likely contain an intellectual property chapter in the end).

190. October 15 Draft, *supra* note 188.

191. *Id.* art. 5.16.

192. *Id.*

193. *See* NAFTA, *supra* note 17, art. 1711.6 (providing coverage against only data reliance).

194. *Compare* October 15 Draft, *supra* note 188, art. 5.16, *with* NAFTA, *supra* note 17, art. 1711.6.

TRIPS Agreement.[195] In short, as far as the protection of test or other data for pharmaceutical products is concerned, the draft RCEP intellectual property chapter will feature a TRIPS-plus obligation that moves the protection standard closer to, and slightly beyond, what NAFTA requires.[196]

Interestingly, the draft RCEP chapter does not include any provision on biologics. The omission is understandable considering the deep controversy surrounding the provision on biologics that arose toward the end of the TPP negotiations.[197] Somewhat surprisingly, the draft chapter also does not include any provision on agrochemical products. Without such a provision, Article 39.3 of the TRIPS Agreement will remain the standard for RCEP partners regarding the protection of undisclosed test or other data for agrochemical products.[198] Thus, the protection will be limited to unfair commercial use and disclosure, and countries will be free to set the duration of such protection.[199]

C. USMCA

In August 2017, the Trump administration began its re-negotiation of NAFTA in Washington, D.C.[200] Signed in December 1992, NAFTA is a trilateral agreement between Canada, Mexico, and the United States.[201] As far as the protection of undisclosed test or other data is concerned, NAFTA is highly important because Articles 1711.5 and 1711.6 provided the United States with a negotiating template to develop Article 39.3 of the TRIPS Agreement.[202] Even more interestingly, NAFTA has provided TRIPS-plus standards in

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195. *See* discussion *supra* text accompanying note 68.

196. *See* Public Citizen, *supra* note 72, at 4-5 (explaining the potential danger created by the market exclusivity provision in the draft RCEP intellectual property chapter).

197. *See* Abbott, *Evolution of Public Health Provisions*, *supra* note 168, at 55 (noting that the negotiation of that provision "was perhaps the most controversial part of the TPP negotiations"); Kilic & Pine, *supra* note 168, at 1 (noting that the negotiation of that provision was "considered 'one of the most difficult outstanding issues in the negotiation' ").

198. TRIPS Agreement, *supra* note 1, art. 39.3.

199. *See* discussion *supra* Section II.A.

200. Press Release, Office of the U.S. Trade Representative, USTR Announces First Round of NAFTA Negotiations (July 19, 2017), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/july/ustr-announces-first-round-nafta [https://perma.cc/3GU7-692F].

201. NAFTA, *supra* note 17.

202. *See* Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 15 (2009) ("NAFTA was a kind of blueprint for the TRIPS Agreement of 1994. It set out, and largely obtained, many of the [intellectual property] objectives that [the United States Trade Representative] hoped to later codify during the Uruguay Round of Multilateral Trade Negotiations."); *see also supra* text accompanying notes 66-68 (discussing the inclusion of NAFTA-like language in the Brussels draft of the TRIPS Agreement).

the area of undisclosed test or other data even before the TRIPS Agreement came into existence.[203]

Initially, Canada was more reluctant than Mexico to complete the renegotiation. At one point, President Trump threatened to abandon Canada and conclude the agreement with Mexico alone.[204] Such a bilateral agreement would reverse the historical picture when Canada and the United States first established an agreement before extending that agreement to Mexico.[205] Nevertheless, Canada eventually reached an agreement with the United States on September 30, 2018.[206] Exactly two months later, the three countries signed the finalized agreement, which has now been named the USMCA.[207] Included in this newly negotiated agreement is Chapter 20, which focuses on the protection and enforcement of intellectual property rights.[208] Out of the ninety provisions in that chapter, three relate to the protection of undisclosed test or other data: Article 20.45 (for agrochemical products),[209] Article 20.48 (for pharmaceutical products),[210] and Article 20.49 (for biologics).[211]

There are many similarities between the TPP and USMCA provisions on the protection of undisclosed test or other data for agrochemical, pharmaceutical, and biological products. Indeed, the USMCA has

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203. *See* Yu, *Data Exclusivities*, *supra* note 11, at 27 ("[E]ven though NAFTA was adopted in 1992 before the TRIPS Agreement, this earlier instrument ended up being a TRIPS-plus agreement in regard to the protection of clinical trial data.").

204. *See* Heather Long, *Trump Threatens to Leave Canada Behind on NAFTA, Warns Congress Not to "Interfere,"* WASH. POST (Sept. 1, 2018), https://www.washingtonpost.com/business/2018/09/01/trumps-playing-tough-with-canadians-he-needs-them/?utm_term=.b2b33b09164b [https://perma.cc/PPJ5-UHHE] (reporting President Trump's warning that the United States would be willing to move forward with a North American trade pact with only Mexico).

205. NAFTA was developed out of the Canada–United States Free Trade Agreement, which Canada and the United States established in January 1988. Canada–United States Free Trade Agreement, Can.-U.S., Jan. 2, 1988, 27 I.L.M. 281.

206. *See* Heather Long, *U.S., Canada and Mexico Just Reached a Sweeping New NAFTA Deal. Here's What's in It.*, WASH. POST (Oct. 1, 2018), https://www.washingtonpost.com/business/2018/10/01/us-canada-mexico-just-reached-sweeping-new-nafta-deal-heres-whats-it/?utm_term=.1469960a085d [https://perma.cc/FN2X-RXUX] (reporting the agreement reached by Canada, Mexico, and the United States).

207. USMCA, *supra* note 16; *see also* Peter K. Yu, *Trump's Trade Policy Is More Predictable and Less Isolationist Than Critics Think*, CONVERSATION (Feb. 1, 2017, 9:57 PM), https://theconversation.com/trumps-trade-policy-is-more-predictable-and-less-isolationist-than-critics-think-72243 [https://perma.cc/3J8C-AX8V] (explaining why trade deals under the Trump administration are unlikely to be developed through a region-based approach, such as an approach based on North America).

208. USMCA, *supra* note 16, ch. 20.

209. *Id.* art. 20.45.

210. *Id.* art. 20.48.

211. *Id.* art. 20.49.

arguably exceeded the TPP obligations,[212] not to mention the CPTPP's suspension of the TPP provisions for undisclosed test or other data for pharmaceutical and biological products.[213] Article 20.45 of the USMCA, which provides protection for agrochemical products, is virtually identical to Article 18.47 of the TPP Agreement.[214] Article 20.48 of the USMCA, which provides protection for pharmaceutical products, also mirrors Article 18.50 of the TPP Agreement.[215]

The main difference between the USMCA and the TPP Agreement has to be the provision on biologics. Article 20.49 of the USMCA includes provisions that align closely with the proposal that U.S. negotiators advanced in the early stages of the TPP negotiations.[216] Instead of requiring protections for "at least eight years from the date of first marketing approval"—as provided for in Article 18.51 of the TPP Agreement[217]—the USMCA offers protection "for a period of at least ten years from the date of first marketing approval of that product in that Party."[218] The USMCA, however, does not retain the second TPP option that allows signatory parties to offer market exclusivity for at least five years and then supplement such exclusivity with "other measures" for the remaining years.[219]

The USMCA biologics provision also omits the review clause in Article 18.51.3 of the TPP Agreement. This review clause provides:

> 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, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to

212. *Compare* USMCA, *supra* note 16, arts. 20.45, 20.48, 20.49, *with* TPP Agreement, *supra* note 12, arts. 18.47, 18.50, 18.51.

213. *See* CPTPP, *supra* note 13, art. 2, Annex (suspending articles 18.50 and 18.51 of the TPP Agreement).

214. *Compare* USMCA, *supra* note 16, art. 20.45, *with* TPP Agreement, *supra* note 12, art. 18.47.

215. *Compare* USMCA, *supra* note 16, art. 20.48, *with* TPP Agreement, *supra* note 12, art. 18.50.

216. *See* Kilic & Pine, *supra* note 168 (discussing the United States' proposal at the TPP negotiations).

217. TPP Agreement, *supra* note 12, art. 18.51.1(a).

218. USMCA, *supra* note 16, art. 20.48.

219. *Compare* TPP Agreement, *supra* note 12, art. 18.51.1(b) (providing this alternative option as a compromise between the different TPP negotiating parties), *with* USMCA, *supra* note 16, art. 20.48 (providing no alternative option).

> ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.[220]

Given that the CPTPP has suspended both Articles 18.50 and 18.51 of the TPP Agreement, Articles 20.48 and 20.49 of the USMCA have revived the TPP provisions as they relate to the trilateral arrangements between Canada, Mexico, and the United States.[221] Although the TPP is still on life support,[222] and it is unclear whether the United States will ever join the CPTPP or revive the now-defunct TPP,[223] the recently completed USMCA negotiations suggest that many of the suspended TPP provisions are not completely dead.[224] In fact, they may return to the international intellectual property arena in some form in the near future.

D. Summary

When the TPP Agreement, the proposed RCEP Agreement, and the USMCA are considered together, one cannot help but notice three important developments that have captured the ongoing contestations over the international minimum standards for intellectual property protection. First, all of these agreements are so-called TRIPS-plus agreements, creating obligations beyond the WTO requirements. While one may question why the RCEP negotiating parties have embraced higher standards than what commentators have claimed would be beneficial to them, their willingness to embrace those standards suggests the slowly evolving internal developments within these countries.[225] It will therefore be interesting to undertake a retrospective ex-

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220. TPP Agreement, *supra* note 12, art. 18.51.3.

221. *See supra* text accompanying notes 182-183.

222. *See* Yu, *Thinking About TPP*, *supra* note 12, at 101-10 (discussing the United States' withdrawal from the TPP Agreement and its aftermath).

223. *See* B.S. Chimni, *Power and Inequality in Megaregulation: The TPP Model*, *in* MEGAREGULATION CONTESTED: GLOBAL ECONOMIC ORDERING AFTER TPP 124, 138 (Benedict Kingsbury et al. eds., 2019) ("[T]he suspended [TPP] provisions may be viewed as bargaining chip to getting the United States on board, allowing it to show some gain in case it agreed to participate in the future."); Letter from Associate Professor Elizabeth Thurbon, University of New South Wales to Joint Standing Committee on Trade, Australian Parliament 5 (Apr. 24, 2018), https://www.aph.gov.au/DocumentStore.ashx?id=3bbbdeab-f37d-4b9b-a34c-8235d69a62d9&subId=565436 ("Australian policymakers will seek to use the suspended provisions as bargaining chips to entice the US back into the TPP-fold, primarily for geo-political reasons.").

224. *See* Yu, *Thinking About TPP*, *supra* note 12, at 106 ("[T]he various chapters in the TPP Agreement, including the intellectual property chapter, will continue to provide the much-needed templates for drafting future bilateral, regional, and plurilateral trade agreements.").

225. *See* discussion *infra* Section IV.B (discussing the changing development in China).

ploration of the contributions of the TRIPS Agreement. Did that Agreement harm developing countries, as many commentators have claimed at the Agreement's adoption twenty-five years ago? Or did that Agreement help these countries by increasing their economic development and technological proficiency?

Second, the different standards between the TPP Agreement, the proposed RCEP Agreement, and the USMCA show the slow transformation of disagreements and contestations into what Kal Raustiala has described as "strategic inconsistenc[ies]."[226] These inconsistencies "occur[] when actors deliberately seek to create inconsistency via a new rule crafted in another forum in an effort to alter or put pressure on an earlier rule."[227] While the multilateral process—such as the one involving the TRIPS Agreement or other WIPO-administered international intellectual property agreements—forced countries to strike compromises, the existence of multiple regional or plurilateral agreements enabled these countries to set norms that best reflect their negotiating power and preferred intellectual property positions. It is small wonder that policymakers and commentators have lamented the growing fragmentation of the international intellectual property regime.[228] As former WTO Director-General Pascal Lamy observed, "proliferation [of plurilateral trade agreements] is breeding concern—concern about incoherence, confusion, exponential increase of costs for business, unpredictability and even unfairness in trade relations."[229] Likewise, WIPO Director General Francis Gurry lamented how the ACTA negotiating parties could have likely "tak[en] matters into their own hands to seek solutions outside of the multilateral system to the detriment of inclusiveness of the present system."[230]

Finally, the intellectual property chapters in the new regional and plurilateral agreements neither result in convergence nor divergence

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226. Kal Raustiala, *Density and Conflict in International Intellectual Property Law*, 40 U.C. DAVIS L. REV. 1021, 1027 (2007).

227. *Id.* at 1027-28 (footnote omitted).

228. *See generally* Eyal Benvenisti & George W. Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60 STAN. L. REV. 595, 596-600 (2007) (discussing the growing "proliferation of international regulatory institutions with overlapping jurisdictions and ambiguous boundaries"); Peter K. Yu, *International Enclosure, the Regime Complex, and Intellectual Property Schizophrenia*, 2007 MICH. ST. L. REV. 1, 13-21 (discussing the development of the "international intellectual property regime complex").

229. Pascal Lamy, Dir.-Gen., World Trade Org., Opening Remarks at the Conference on "Multilateralizing Regionalism" in Geneva (Sept. 10, 2007), http://www.wto.org/english/news_e/sppl_e/sppl67_e.htm [https://perma.cc/6CTS-2XNV].

230. Catherine Saez, *ACTA a Sign of Weakness in Multilateral System, WIPO Head Says*, INTELL. PROP. WATCH (June 30, 2010), http://www.ip-watch.org/weblog/2010/06/30/acta-a-sign-of-weakness-in-multilateral-system-wipo-head-says/ [https://perma.cc/HDT9-C7SB].

of international intellectual property standards—a question that is often asked in regard to these agreements.[231] Consider, for instance, the comparison between the TPP intellectual property chapter and the draft RCEP intellectual property chapter.[232] While the negotiations for the former were heavily driven by the United States, the negotiations for the latter feature China and India, two leaders in the developing world.[233] Given the differences, one naturally would expect the RCEP standards to be much lower than their TPP counterparts. Although some RCEP standards are indeed lower than TPP standards, others are the same—while some are even higher.[234] Given this dizzying array of identical, converging, and diverging standards, I have recently coined the term "crossvergence" to describe the complicated phenomenon in which different standards have now been included through the norm-setting exercises advanced by the TPP and the RCEP.[235] These exercises result in neither convergence nor divergence of regulatory standards, but the simultaneous convergence and divergence—or crossvergence—of these standards.[236]

IV. ADDITIONAL COMPLICATIONS

As far as international intellectual property agreements are concerned, commentators have a tendency to focus on developments that affect the scope, duration, and limitations of the stipulated rights.[237]

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231. *See generally* GOVERNING SCIENCE AND TECHNOLOGY, *supra* note 12 (collecting articles that explore whether the development of new mega-regional agreements has led to regulatory convergence or divergence).

232. *See* discussion *supra* Sections III.A and III.B.

233. *See* Peter K. Yu, *Clusters and Links in Asian Intellectual Property Law and Policy*, *in* ROUTLEDGE HANDBOOK OF ASIAN LAW 147, 150 (Christoph Antons ed., 2017) ("Lacking a regional hegemon, Asia is filled with developments spearheaded by three different leaders: China, India, and Japan."); Yu, *Copyright Norm-setting*, *supra* note 12, at 42 ("While the TPP and the CPTPP evidence the leadership of the United States and Japan, respectively, many policymakers and commentators consider the RCEP a China-led mega-regional agreement."). *See generally* Yu, *Norm Setters*, *supra* note 15 (discussing the role played by China, India, and other Asian norm setters in the RCEP negotiations).

234. *See* Yu, *Crossvergence*, *supra* note 12, at 292-93 (noting that the draft RCEP intellectual property chapter includes TPP-plus, TPP-like, and TPP-minus provisions).

235. *See id.* at 277. The concept of crossvergence draws on literature in other disciplines. A widely cited example in the international management literature is David A. Ralston, *The Crossvergence Perspective: Reflections and Projections*, 39 J. INT'L BUS. STUD. 27 (2007).

236. *See* Yu, *Crossvergence*, *supra* note 12, at 278 ("[Asia] is likely to see 'regulatory crossvergence'—a simultaneous convergence and divergence of regulatory standards. Such crossvergence not only has resulted in the region's development of compromising standards but has also been highly indicative of the ongoing and future standard-setting efforts in Asia.").

237. *See, e.g.*, H.R. REP. NO. 100-609, at 12-13 (1988) (providing a brief overview of the different revision acts of the Berne Convention for the Protection of Literary and Artistic Works).

As the two previous Parts already cover the contestations over the international minimum standards for protecting undisclosed test or other data for pharmaceutical and agrochemical products, this Part addresses three sets of additional complications that have affected the development of international minimum standards in this area: new technologies, new politics, and new regulatory spillovers. Depending on the specific development, these complications can either help or harm the TRIPS harmonization project by increasing or reducing contestation.

A. New Technologies

Legal standards have always lagged behind technology. Language in international treaties has lagged behind even further. As I have noted in an earlier book chapter, "from initial negotiation to final ratification to full implementation, it takes a considerable amount of time, effort, energy, and resources to complete a trade agreement. The rate at which such an agreement is developed can hardly keep pace with the rate of technological change."[238] Likewise, Colin Picker cautioned: "[D]elay is the rule in the formation of international law. Usually, international law is created over long periods, by the gradual acceptance of customary state practice or after long treaty negotiations."[239]

In recent years, two new technological developments have deeply affected the protection of undisclosed test or other data for pharmaceutical and agrochemical products. The first development concerns the emergence of big-data analytics, which "has transformed the fields of biotechnology and bioinformatics while ushering in major advances in drug development, clinical practices, and medical financing."[240] As data become more valuable, leading to such a hyperbole as "data is the

238. Peter K. Yu, *Trade Agreement Cats and the Digital Technology Mouse*, *in* SCIENCE AND TECHNOLOGY IN INTERNATIONAL ECONOMIC LAW: BALANCING COMPETING INTERESTS 185, 202 (Bryan Mercurio & Ni Kuei-Jung eds., 2014).

239. Colin B. Picker, *A View from 40,000 Feet: International Law and the Invisible Hand of Technology*, 23 CARDOZO L. REV. 149, 184 (2001).

240. Yu, *Data Exclusivities*, *supra* note 11, 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/3NG3-2765] ("In research and development . . . big data and analytics are being adopted across industries, including pharmaceuticals.").

new oil,"[241] it is understandable why those who develop undisclosed test or other data for pharmaceutical or agrochemical products would prefer stronger protection for such data. After all, the more protection they secure, the more value they can extract from these data. Such value extraction has become especially complicated when a considerable portion of the value lies in the reuse, or initially unintended use, of those data.[242]

Moreover, the use of big-data analytics in pharmaceutical and agrochemical industries may require the provision of new incentives to motivate these industries to upgrade legacy technology and to invest in new analytical tools to optimize innovation, improve clinical trial efficiency, and strengthen product quality, safety, and efficacy.[243] With

241. " 'Data is the new oil', a phrase that is common currency among leaders in industry, commerce, and politics, is usually attributed to Clive Humby in 2006, the originator of Tesco's customer loyalty card." DAWN E. HOLMES, BIG DATA: A VERY SHORT INTRODUCTION 20 (2017); *see also* MAYER-SCHÖNBERGER & CUKIER, *supra* note 74, at 16 (describing data as "the oil of the information economy"); Teresa Scassa, *Data Ownership* 1 (Ctr. for Int'l Governance Innovation, CIGI Paper No. 187, 2018) ("The commercial value and importance of data is such that they have been referred to as the 'new oil' . . . ."); *The World's Most Valuable Resource Is No Longer Oil, but Data*, ECONOMIST (May 6, 2017), https://www.economist.com/news/leaders/21721656-data-economy-demands-new-approach-antitrust-rules-worlds-most-valuable-resource [https://perma.cc/RY4S-9X79] (stating that data have "spawn[ed] a lucrative, fast-growing industry [the same way as oil], prompting antitrust regulators to step in to restrain those who control its flow"). *But see* HOLMES, *supra*, at 20 ("[U]nlike oil, data appears not to be a finite resource."); Lauren Henry Scholz, *Big Data Is Not Big Oil: The Role of Analogy in the Law of New Technologies* (Fla. State Univ. Coll. of Law Pub. Law & Legal Theory Working Paper Grp., Paper No. 895, 2019), https://ssrn.com/abstract=3252543 [https://perma.cc/D8MQ-9CG5] (challenging the data-as-oil analogy); ORG. FOR ECON. CO-OPERATION & DEV., DATA-DRIVEN INNOVATION: BIG DATA FOR GROWTH AND WELL-BEING 179-80 (2015) (discussing data as a non-rivalrous good); JEROME H. REICHMAN ET AL., GOVERNING DIGITALLY INTEGRATED GENETIC RESOURCES, DATA, AND LITERATURE: GLOBAL INTELLECTUAL PROPERTY STRATEGIES FOR A REDESIGNED MICROBIAL RESEARCH COMMONS 434-35 (2016) (noting that publicly funded research data and information "gains in value from broad dissemination and . . . is reusable"); Scassa, *supra*, at 1 ("[M]any are quick to point out that data are an infinitely renewable resource.").

242. *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"); MAYER-SCHÖNBERGER & CUKIER, *supra* note 74, at 153 ("[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.").

243. *See* W. Nicholson Price II, *Big Data, Patents, and the Future of Medicine*, 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 240 (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

these costly expenditures,[244] one can only assume that private industries would want stronger protection of their proprietary data to help recoup those up-front investments.

Notwithstanding the immense and ever-growing value of undisclosed test or other data for pharmaceutical and agrochemical products, one cannot forget that accurate and reliable big-data analyses require the existence of large, comprehensive datasets. As Viktor Mayer-Schönberger and Kenneth Cukier observed, "big data relies on all the information, or at least as much as possible."[245] Moreover, because of the changing nature of our technological environment, many relevant data now reside in separate datasets and often in multiple data storage systems.[246] In the past decade, computer scientists and engineers have worked tirelessly to develop ways to analyze data without moving them from one storage system to another.[247] Thus, if the ability to undertake big-data analyses is to be maximized, such analyses will require greater sharing of data. Indeed, providing property-like protection to undisclosed test or other data could fragment the

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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://www.geektime.com/2017/05/08/5-ways-big-data-is-transforming-the-pharmaceutical-industry/ [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.").

244. *See* Nichols, *supra* note 243 ("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.").

245. MAYER-SCHÖNBERGER & CUKIER, *supra* note 74, at 30.

246. *See* JAMES MANYIKA ET AL., MCKINSEY GLOB. INST., BIG DATA: THE NEXT FRONTIER FOR INNOVATION, COMPETITION, AND PRODUCTIVITY 12 (2011) ("To enable transformative opportunities, companies will increasingly need to integrate information from multiple data sources."); MAYER-SCHÖNBERGER & CUKIER, *supra* note 74, at 46 ("Large datasets do not exist in any one place; they tend to be split up across multiple hard drives and computers."); Riley, *supra* note 242, at 254 ("One of the biggest challenges for Big Data [in the healthcare space] is linking data from multiple sources so that data describing an individual located in one source are linked with data about the same individual in other sources."); Michal S. Gal & Daniel L. Rubinfeld, *Data Standardization*, 94 NYU L. REV. (forthcoming 2019) (manuscript at 3), https://ssrn.com/abstract=3326377 [https://perma.cc/8DWZ-4TDR] ("[C]onsider medical data on patients' responses to a treatment for a rare disease. Unless data was shared among its collectors and combined into a coherent dataset, it would be difficult to reach a better understanding of how to treat the disease.").

247. *See* JOHN D. KELLEHER & BRENDAN TIERNEY, DATA SCIENCE 78-80 (2018) (discussing Hadoop and other efforts to move the algorithms to the data, as opposed to moving the data themselves); PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., EXEC. OFFICE OF THE PRESIDENT, BIG DATA AND PRIVACY: A TECHNOLOGICAL PERSPECTIVE 30 (2014) ("Specialized software technology allows the data in multiple data centers (and spread across tens of thousands of processors and hard-disk drives) to cooperate in performing the tasks of data analytics, thereby providing both scaling and better performance.").

data market,[248] creating what Rebecca Eisenberg and Michael Heller have described as the "tragedy of the anti-commons."[249]

The second new technological development, which "has . . . revolutionized the healthcare and pharmaceutical industries," is the growing importance and popularity of biologics and personalized medicines.[250] Thus far, commentators have noted the challenge in obtaining sufficient protection for these products through the patent system.[251] Because biologics involve biological materials, as opposed to chemicals, their protections often need to rely on process patents rather than product patents.[252] In addition, Article 39.3 of the TRIPS Agreement

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248. *See* Josef Drexl, *Designing Competitive Markets for Industrial Data—Between Propertisation and Access*, 8 J. INTELL. PROP. INFO. TECH. & ELECTRONIC 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").

249. For discussions of the tragedy of the anti-commons, see generally MICHAEL HELLER, THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES 49-78 (2010); Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

250. Yu, *Data Exclusivities*, *supra* note 11, at 22.

251. *See* Heled, *supra* note 119, at 450-61 (discussing why patents may not provide sufficient protection to biologics).

252. As Nicholson Price explained:

> For biological manufacturing processes, patent protection strategies may differ because manufacturing methods are unusually central for biologics. Even more so than for small-molecule drugs, the manufacturing complexity and development costs for biologics can serve as a potent barrier to entry, keeping competitors off the market. Thus, the 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. Despite the risks of disclosure, some firms pursue process patents.

W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 527 (2014) (footnotes omitted); *see also* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1051 (2016) ("[B]ecause biologics cannot be described precisely by structure, the only composition-of-matter patents that should be allowed on biologics are so-called product-by-process patents. These patents are essentially process patents, as the patentee's coverage is limited to the particular method it has used." (footnote omitted)); Trevor Woodage, *Blinded by (a Lack of) Science: Limitations in Determining Therapeutic Equivalence of Follow-on Biologics and Barriers to Their Approval and Commercialization*, 2012 STAN. TECH. L. REV. 9, at 15 (noting that "[t]he products of biologics patents are generally closely related to substances that already exist in the human body and broad composition of

does not grant protection to biologics because those products are not considered "new chemical entities" within the meaning of the Agreement.[253] The insufficient protection provided by the TRIPS Agreement indeed explains why the European Union, Japan, and the United States have eagerly pushed for specific provisions relating to biologics in bilateral, regional, and plurilateral trade negotiations.[254]

Despite the developed countries' active push for new international norms to protect biologics, it remains difficult to determine ex ante whether stronger protections in this ever-evolving field would accelerate or stifle the future development of biologics and personalized medicines. It is equally unclear whether the existing models in the European Union or the United States would provide suitable "transplants" for other countries.[255] Given this uncertainty, it is no surprise that efforts to set the standards for protecting biologics have been highly controversial toward the end of the TPP negotiations.[256] With the United States' withdrawal from the TPP, the eleven remaining TPP partners quickly suspended Article 18.51, which likely would not have been adopted without the heavy pressure exerted by U.S. negotiators.[257] As

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matter claims are usually disallowed for proteins that already exist in nature," and that "biologics developers may need to rely on protections offered by process patents").

253. *See* Ragavan, *(Re)Newed Barrier*, *supra* note 62, at 1185 ("On the face of it, biologics are not included within the scope of Article 39.3's requirement to protect new chemical entities. The [new chemical entities] should not, by definition, include biologics." (footnote omitted)). As Professor Ragavan explained:

> Considering that data exclusivity is for "new" "chemical" entities, it would be harder to justify data protection for biologics that are denied patent protection because they lack novelty on account of falling within the scope of "naturally occurring products." There is nothing in Article 39 that requires something that is not considered "new" in patent law to be treated as "new" for the purpose of data exclusivity.

Id. at 1186.

254. *See, e.g.*, TPP Agreement, *supra* note 12, art. 18.51 (introducing a marketing exclusivity regime to protect biologics).

255. For discussions of legal transplants, see generally ALAN WATSON, LEGAL TRANSPLANTS: AN APPROACH TO COMPARATIVE LAW (2d ed. 1993); Peter K. Yu, *The Transplant and Transformation of Intellectual Property Laws in China*, *in* GOVERNANCE OF INTELLECTUAL PROPERTY RIGHTS IN CHINA AND EUROPE 20 (Nari Lee et al. eds., 2016); Paul Edward Geller, *Legal Transplants in International Copyright: Some Problems of Method*, 13 UCLA PAC. BASIN L.J. 199 (1994); Otto Kahn-Freund, *On Uses and Misuses of Comparative Law*, 37 MOD. L. REV. 1 (1974); Peter K. Yu, *Can the Canadian UGC Exception Be Transplanted Abroad?*, 26 INTELL. PROP. J. 175 (2014); Peter K. Yu, *Customizing Fair Use Transplants*, 7 LAWS 9, at 5-7 (2018), http://www.mdpi.com/2075-471X/7/1/9 [https://perma.cc/MM96-PN7C]; Peter K. Yu, *Digital Copyright Reform and Legal Transplants in Hong Kong*, 48 U. LOUISVILLE L. REV. 693 (2010); Peter K. Yu, *Fair Use and Its Global Paradigm Evolution*, 2019 U. ILL. L. REV. 111.

256. *See supra* authorities cited in note 168.

257. *See* discussion *supra* text accompanying note 183.

to the RCEP negotiations, provisions regarding the protection of biologics did not even make it to the leaked October 2015 draft.[258] If TPP-like language had been advanced before that draft, such language did not seem to have generated enough traction or support to allow it to continue into the tenth negotiation round in Busan, South Korea in October 2015.[259]

Taken together, these two new technological developments illustrate some of the nonlegal challenges countries may likely encounter in setting international norms for protecting undisclosed test or other data for pharmaceutical and agrochemical products. Policymakers and negotiators not only need to determine the appropriate scope, duration, and limitations of the stipulated rights but they should also anticipate what new technologies will emerge and how these technologies will affect the pharmaceutical and agrochemical industries. To help avoid overprotection, unnecessary complications, and unintended consequences, I have called on "policymakers and commentators [to] carefully tailor [any] new protection [in this area] to only those areas that have empirically proven needs."[260] Even if stronger protection of undisclosed test or other data would be beneficial to select products—biologics and orphan drugs, perhaps[261]—such protection should not automatically extend across the board to all pharmaceutical and agrochemical products.

B. New Politics

While the arrival of new technologies has undoubtedly generated challenges to the TRIPS harmonization project and efforts to set new international intellectual property norms, changing positions in the

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258. October 15 Draft, *supra* note 188.

259. *See Tenth Round of Negotiations—12-16 October 2015, Busan, Korea*, AUSTL. GOV'T DEP'T FOREIGN AFF. & TRADE (Oct. 16, 2015), https://dfat.gov.au/trade/agreements/negotiations/rcep/news/Pages/tenth-round-of-negotiations-12-16-october-2015-busan-korea.aspx [https://perma.cc/JJ9S-9CCR] (providing a brief recap of the tenth round of RCEP negotiations in Busan, South Korea during October 12-16, 2015).

260. Yu, *Data Exclusivities*, *supra* note 11, at 32; *see also* P. Bernt Hugenholtz, *Against "Data Property," in* 3 KRITIKA: ESSAYS ON INTELLECTUAL PROPERTY 48, 70 (Hanns Ullrich et al. eds., 2018) ("Any new right should be contemplated only after conducting thorough economic, evidence-based research that demonstrates a real need for the right and predicts its consequences for information markets and society at large."); WILLIAM PATRY, HOW TO FIX COPYRIGHT 52 (2012) (noting the need for "mandatory, independently-produced, impartial, empirically rigorous impact statements *before* any new copyright legislation is passed"); Peter K. Yu, *Digital Copyright and Confuzzling Rhetoric*, 13 VAND. J. ENT. & TECH. L. 881, 918-22 (2011) (noting the need for the proponents of intellectual property reform to provide credible empirical support).

261. *See* Skillington & Solovy, *supra* note 37, at 9-10 (discussing the Orphan Drug Act and how it has helped to increase the supply of drugs to treat rare diseases).

developing world have also greatly complicated the negotiating picture. Indeed, as far as international intellectual property negotiations are concerned, the traditional North-South divide has become increasingly untenable.

To be sure, there remains significant and continuous disagreement between developed and developing countries over the appropriate level of intellectual property protection and enforcement, which has resulted in the extension of the TRIPS transition periods[262] and the expansion of the compulsory licensing arrangement through the newly adopted Article 31*bis* of the TRIPS Agreement.[263] Nevertheless, the positions of developing countries are slowly evolving. While the willingness of China, India, and other large developing countries to accept higher intellectual property standards in the RCEP negotiations reflects this evolving picture,[264] China's recent proposal for higher standards for protecting undisclosed test or other data for pharmaceutical and biological products is particularly revealing.[265]

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262. *See* Yu, *Virotech Patents*, *supra* note 61, at 1568 (noting the extension of TRIPS transition periods). For discussions of these transition periods, see generally Frederick M. Abbott, *Technical Note: The LDC TRIPS Transition Extension and the Question of Rollback* (ICTSD Programme on Innovation, Technology and Intellectual Property, Policy Brief No. 15, 2013), http://ictsd.org/downloads/2013/05/the-ldc-trips-transition-extension-and-the-question-of-rollback.pdf [https://perma.cc/7BJM-92MN]; Arno Hold & Bryan Christopher Mercurio, *After the Second Extension of the Transition Period for LDCs: How Can the WTO Gradually Integrate the Poorest Countries into TRIPS?* (NCCR Trade Regulation, World Trade Institute, University of Bern, Working Paper No. 2013/42, 2013), http://ssrn.com/abstract=2302335 [https://perma.cc/J2GW-MYJE].

263. General Council, *supra* note 107.

264. As I noted in an earlier article:

> China, India, and other emerging countries within ASEAN+6 . . . have begun to appreciate the strategic benefits of stronger intellectual property protection and enforcement. Although these countries have yet to embrace the very high protection and enforcement standards found in the European Union, Japan, or the United States, they now welcome standards that are higher than what is currently available in the Asia-Pacific region.

Yu, *RCEP and Trans-Pacific Norms*, *supra* note 15, at 722.

265. It is worth noting that China does not have all the flexibilities available under Article 39.3 of the TRIPS Agreement. When China acceded to the WTO, it accepted a WTO-plus obligation that does not allow for data reliance. As the report of the Working Party on the Accession of China stated:

> The representative of China . . . confirmed that China would, in compliance with Article 39.3 of the TRIPS Agreement, provide effective protection against unfair commercial use of undisclosed test or other data submitted to authorities in China as required in support of applications for marketing approval of pharmaceutical or of agricultural chemical products which utilized new chemical entities, except where the disclosure of such data was necessary to protect the public, or where steps were taken to ensure that the data are protected against unfair commercial use. This protection would include introduction and enactment of laws and regulations to make sure that no person, other than the person who submitted such data, could, without the permission of the person who submitted

Under this proposal, China will provide six years of protection to data submitted for regulatory approval of innovative drugs (*chuangxin yao*).[266] The country will further offer twelve years of protection to data submitted for regulatory approval of innovative therapeutic biologics (*chuangxin zhiliao yong shengwu zhipin*).[267] As if the proposal for increased protection of undisclosed test or other data were not appealing enough to the pharmaceutical industry, China is currently considering a limited extension of the patent term based on the period during which a pharmaceutical product undergoes regulatory review,[268] similar to what is provided under the Hatch-Waxman Act of 1984 in the United States.[269] It is therefore no surprise that seasoned China observer Mark Cohen described these recent developments as "one of several exciting new developments in the pharma [intellectual property] sector in China."[270]

These recent reform proposals are globally significant for three reasons. First, they show that China is no longer content serving as a supplier of active pharmaceutical ingredients, even though it has already

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> the data, rely on such data in support of an application for product approval for a period of at least six years from the date on which China granted marketing approval to the person submitting the data. During this period, any second applicant for market authorization would only be granted market authorization if he submits his own data. This protection of data would be available to all pharmaceutical and agricultural products which utilize new chemical entities, irrespective of whether they were patent-protected or not. The Working Party took note of these commitments.

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

266. Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products art. 5, https://chinaipr2.files.wordpress.com/2018/04/draftdataexclusivityrules.doc [https://perma.cc/HS3Y-6SYY] (China).

267. *Id.*

268. *See* Patent Law of People's Republic of China (Draft) art. 43 (2019) [hereinafter Draft Fourth Amendment], *translated at* https://chinaipr2.files.wordpress.com/2019/01/2019-draft-patent-law-amendment-line-by-line-en-and-cn-by-anjie.doc [https://perma.cc/W4AR-Y5PH] (providing up to five years of extension of the patent term for innovative drugs); *see also* Tim Jackson, *China to Allow Patent Extension of Term?*, ROUSE (May 16, 2018), https://www.rouse.com/magazine/news/china-to-allow-patent-extension-of-term/ [https://perma.cc/U9CG-9LAR] (discussing the potential extension of the patent term for pharmaceutical products in China).

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

270. 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/BY9C-FN45].

been the world's largest supplier of these ingredients[271] and second largest pharmaceutical market.[272] Instead, China wants to develop a research-based pharmaceutical industry.[273] Its position in this area is consistent with those in other areas. Since the State Council adopted the National Intellectual Property Strategy in June 2008,[274] China has taken an innovative turn. Paragraph 7 of that strategy specifically emphasized the need for active development of independent intellectual property (*zizhu zhishi chanquan*).[275] Section V of the *Outline of the National Medium- and Long-Term Plan for Science and Technology Development (2006–2020)*, which the State Council released in February 2006, also included biotechnology among the eight distinct types of frontier technologies—which also include information technology, advanced materials, advanced manufacturing, advanced energy technology, marine technology, laser technology, and aerospace technology.[276]

Second, the position China is now taking contrasts sharply with the position taken by India—another leader of the developing world. As my colleague Srividhya Ragavan and other commentators have observed, India remains skeptical of the benefits provided by strong protections for undisclosed test or other data for pharmaceutical and biological products.[277] To a large extent, the position India now takes is

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271. *See* Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 363 (2008) [hereinafter Yu, *Access to Medicines*] (noting that China "is the world's largest producer of active pharmaceutical ingredients").

272. *See* Issaku Harada, *China Extends Drug Patents to 25 Years*, NIKKEI ASIAN REV. (May 16, 2018), https://asia.nikkei.com/Politics/China-extends-drug-patents-to-25-years [https://perma.cc/6RV5-8H2T] ("China's pharmaceutical market is now worth more than $120 billion, second only to America's.").

273. *Cf.* LI YAHONG, IMITATION TO INNOVATION IN CHINA: THE ROLE OF PATENTS IN BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES 54 (2010) ("China has advantages in producing 'me too' drugs because its capacity to conduct organic synthesis is very strong after many years of China's being the target for outsourced [multinational pharmaceutical companies'] business.").

274. *See* THE STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, OUTLINE OF THE NATIONAL INTELLECTUAL PROPERTY STRATEGY (2008) [hereinafter NATIONAL INTELLECTUAL PROPERTY STRATEGY], http://www.gov.cn/english/2008-06/21/content_1023471.htm [https://perma.cc/GKX8-98Z8] (providing the outline of a new national intellectual property strategy); *see also* Peter K. Yu, *A Half-Century of Scholarship on the Chinese Intellectual Property System*, 67 AM. U. L. REV. 1045, 1079-85 (2018) (discussing the National Intellectual Property Strategy).

275. NATIONAL INTELLECTUAL PROPERTY STRATEGY, *supra* note 274, ¶ 7.

276. THE STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, THE NATIONAL MEDIUM- AND LONG-TERM PLAN FOR SCIENCE AND TECHNOLOGY DEVELOPMENT (2006–2020): AN OUTLINE § V (2006), https://www.itu.int/en/ITUD/Cybersecurity/Documents/National_Strategies_Repository/China_2006.pdf [https://perma.cc/8FK3-WYNC].

277. As Professor Ragavan declared emphatically:

> [D]ata exclusivity as a tool detrimentally affects generic competition. Thus, it is no coincidence that India has been pressurized by the [United States Trade Representative] to extend the existing 4 year period of data exclusivity to 10 years.

not that different from the strong opposition it had mounted during the TRIPS negotiations.[278] Out of the four draft texts for the RCEP intellectual property chapter introduced by the negotiating parties,[279] the text from India aligned most closely with the traditional position taken by developing countries.[280] China, by contrast, did not offer any proposed text despite having a dominant position in the RCEP negotiations.[281] Although the country and the population at large remain deeply concerned about the lack of access to essential medicines—as reflected in the recent blockbuster Chinese movie *Dying to Survive*[282]—the country's official position during international negotiations and in policy debates has evolved considerably.

Finally, China is not only eager to develop its research-based drug industry but is also hoping to use its new laws and policies to attract

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> For countries like India, it is good to appreciate that generics have become a part of the global pharmaceutical industry.

Ragavan, *Data Exclusivity*, *supra* note 41, at 260 (footnote omitted); *see also* Ragavan, *(Re)Newed Barrier*, *supra* note 62, at 1188 (discussing the four years of data exclusivity protection provided by Section 122E of the Indian Drugs and Cosmetics Act of 1940); Srividhya Ragavan, *The Significance of the Data Exclusivity and Its Impact on Generic Drugs*, 1 J. INTELL. PROP. STUD. 131, 140 (2017) (arguing that "India has a perfectly fine data exclusivity provision" and does not need to strengthen protection in this area); Prashant Reddy T., *The Data Exclusivity Debate in India: Time for a Rethink?*, 10 INDIAN J.L. & TECH. 8, 17-25 (2014) (capturing the debate in India on the protection of undisclosed test or other data for pharmaceutical and agrochemical products).

278. *See* WATAL, *supra* note 11, at 19 (discussing the role of hardliner countries at the TRIPS negotiations); Yu, *Currents and Crosscurrents*, *supra* note 8, at 359 & n.195 (discussing the hardliner countries such as "Argentina, [Brazil], Cuba, Egypt, [India], Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia").

279. *See* Yu, *RCEP and Trans-Pacific Norms*, *supra* note 15, at 683-84 (noting the submission of the draft texts).

280. *See* Gov't of India, *Working Draft of IPR Chapter from India: RCEP Negotiations* (Oct. 2014), http://keionline.org/sites/default/files/06-RCEP-TNC6-WGIP3-IN-IP-Draft.pdf [https://perma.cc/4JVA-FBSZ]; *see also* James Love, *2014 Oct 10: ASEAN Proposals for RECP IP Chapter, Also India*, KNOWLEDGE ECOLOGY INT'L (June 8, 2015), http://keionline.org/node/2241 [https://perma.cc/MX2B-QCDF] (providing the leaked proposal from India).

281. As I previously noted:

> In regard to the draft RCEP chapter, . . . China did not even advance a proposal. As revealed by Knowledge Ecology International, the draft proposals came from other negotiating parties—namely, ASEAN, India, Japan and South Korea. The only area in which China has taken a more assertive position concerns the disclosure in patent applications of the source of origin of genetic resources used in the inventions, a requirement that already exists in art 26 of the Chinese Patent Law.

Yu, *Copyright Norm-setting*, *supra* note 12, at 43 (footnotes omitted); *see also* Anupam Chander & Madhavi Sunder, *The Battle to Define Asia's Intellectual Property Law: From TPP to RCEP*, 8 U.C. IRVINE L. REV. 331, 358 (2018) (showing that China is the country that is the least eager to insert a comment on the RCEP text).

282. DYING TO SURVIVE [WO BU SHI YAOSHEN] (Dirty Monkey Films Group 2018). *Wo bu shi yaoshen* translates to "I am not God of Medicine."

foreign pharmaceutical manufacturers.[283] Stronger protections for undisclosed test or other data for pharmaceutical and biological products will certainly make China a much more appealing place for conducting clinical trials.[284] Should foreign pharmaceutical manufacturers decide to relocate their R&D facilities to China, they will join the electronic and other industries in moving research centers and other facilities to China.[285] Such relocation will most certainly have a significant global impact.

C. New Regulatory Spillovers

When the TRIPS Agreement was adopted, intellectual property issues were "arcane, obscure, complex, and highly technical."[286] As Susan Sell observed, those issues were "reminiscent of the Catholic Church when the Bible was in Latin."[287] However, as people became more conscious of intellectual property issues and as policymakers became more comfortable in handling intellectual property matters, we began to see the use of international regulatory standards outside the intellectual property area to address intellectual property disputes and questions.

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283. *See, e.g.*, Draft Fourth Amendment, *supra* note 268; Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products, *supra* note 266.

284. *See* Cohen, *supra* note 270 ("As a policy matter, [the proposed Provisional Measures for the Implementation of Test Data Protection for Pharmaceutical Products] appears intended to help encourage conducting clinical trials in China as well as new product introduction into the Chinese market[.]").

285. As Zeng Ming and Peter Williamson recounted:

> [Since 1993], Motorola has built sixteen R&D centers with more than eighteen hundred people. In 1999, Motorola set up its China Research Institute in Beijing, which is among the largest facilities of its type in China, and also a world-class center within Motorola. Between 1985 and 2003, Motorola has applied for 2,305 patents, making it among the biggest patent applicants in China. . . .
>
> Recognizing that it needs to leverage Chinese advantages at every stage of the value chain in order to strengthen its global competitiveness, Korea's LG group has gone even further, moving key R&D to China. In 2005 LG hired two thousand engineers and scientists into its Chinese R&D center, making it LG's largest R&D site outside Korea. LG has submitted more worldwide patent applications based on research conducted in China than any other company, with the exception for Huawei. By placing such emphasis on China-based R&D, LG is tapping into the secrets of how to deliver high technology at low cost to strengthen and differentiate its competitive position against rivals such as Sony, Matsushita, and its archrival Samsung.

ZENG MING & PETER J. WILLIAMSON, DRAGONS AT YOUR DOOR: HOW CHINESE COST INNOVATION IS DISRUPTING GLOBAL COMPETITION 178-79 (2007).

286. Yu, *Currents and Crosscurrents*, *supra* note 8, at 419.

287. SELL, *supra* note 22, at 99.

Indeed, the negotiation of the TRIPS Agreement has provided a paradigmatic example of the complications posed by linking the international intellectual property regime with another international regime—in this case, the trade regime.[288] While the traditional discussion of intellectual property issues focuses on incentives, the incentives question is less central to an inquiry when these issues are explored through a trade lens.[289] Oftentimes, policymakers and trade negotiators see intellectual property protection as a mere bargaining chip. As Michael Geist observed more than a decade ago, in relation to the free trade agreement negotiations between the United States and the Dominican Republic and between the United States and Australia:

> Developing countries such as the Dominican Republic view the inclusion of stronger copyright protections as a costless choice. For those countries, the harm that may result from excessive copyright controls pales in comparison to more fundamental development concerns and they are therefore willing to surrender copyright policy decisions in return for tangible benefits in other trade areas.
>
> Developed countries such as Australia may recognize the importance of a balanced copyright policy to both their cultural and economic policies, but they are increasingly willing to treat intellectual property as little more than a bargaining chip as part of broader negotiation. Since most trade deals are judged by an analysis of the bottom-line, economic benefits that result from the agreement, and since quantifying the negative impact of excessive copyright controls is difficult, the policy implications of including copyright within trade agreements is often dismissed as inconsequential.[290]

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288. As I noted in an earlier article:

> [The TRIPS Agreement] not only transformed the international intellectual property landscape but also necessitated a revision—and for many countries, a complete overhaul—of the domestic intellectual property system. It is therefore no surprise that some leading commentators have described the TRIPS Agreement as a "sea change" or "tectonic shift" in international intellectual property law and policy.
>
> Today, we are at a similar crossroads. Through bilateral, regional, and plurilateral trade and investment agreements, new norms are being developed to address the investment-related aspects of intellectual property rights. Even more importantly, these norms will strengthen the ability of private investors, such as intellectual property rights holders, to sue foreign governments without the support of their home governments. One therefore cannot help but wonder whether we are now approaching yet another "sea change" or "tectonic shift" in international intellectual property law and policy.

Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 AM. U. L. REV. 829, 831 (2017) [hereinafter Yu, *Investment-Related Aspects*] (footnotes omitted).

289. *See* Yu, *The International Enclosure Movement*, *supra* note 5, at 892-901 (discussing an emerging "incentive-investment divide").

290. Michael Geist, *Why We Must Stand on Guard Over Copyright*, TORONTO STAR, Oct.

In recent years, investment law has also rudely entered the intellectual property domain. Notable examples are the recent investor-state disputes involving Philip Morris and Australia,[291] Philip Morris and Uruguay,[292] Eli Lilly and Canada,[293] and Bridgestone and Panama.[294] Indeed, with the arrival of these disputes, one cannot help but wonder "whether we are now approaching yet another 'sea change' or 'tectonic shift' in international intellectual property law and policy,"[295] similar to what we experienced when intellectual property was married to trade through the TRIPS Agreement twenty-five years ago.[296]

20, 2003, at D3. Josef Drexl concurred:

> Even if the members of parliament understand the full social implications of the [new trade] agreement, the situation in which they have to make their decision is substantially different from adopting autonomous [intellectual property] legislation. Even more than their governments, national parliaments are confronted with the political strategy of the package approach that does not allow for an unbundling of the different topics covered by comprehensive free trade agreements. The question before the parliaments is not how to balance most appropriately the conflicting interests of different stakeholders in the framework of national [intellectual property] legislation, but how to assess and balance the social costs and benefits of such agreements. While the governments at least have a chance to influence the outcome of the negotiations of bilateral trade agreements, the parliaments can only give the approval to an agreement in its entirety or reject it.

Josef Drexl, *The Concept of Trade-Relatedness of Intellectual Property Rights in Times of Post-TRIPS Bilateralism*, *in* TRIPS PLUS 20: FROM TRADE RULES TO MARKET PRINCIPLES 53, 76 (Hanns Ullrich et al. eds., 2016); *see also* Shira Perlmutter, *Future Directions in International Copyright*, 16 CARDOZO ARTS & ENT. L.J. 369, 378 (1998) (contending that, for many countries, "the trade-related benefits that may be obtained from joining a club like the WTO can outweigh any perceived drawbacks of adopting a new copyright law"); Yu, *Access to Medicines*, *supra* note 271, at 386 ("Many policymakers in less developed countries are . . . blinded by the benefits their countries *may* receive in other trade areas under a package deal . . . .").

291. *See* Philip Morris Asia Ltd. v. Commonwealth of Austl., PCA Case No. 2012-12, Award on Jurisdiction and Admissibility (Dec. 17, 2015) (using the investor-state dispute settlement mechanism in the bilateral agreement between Australia and Hong Kong to challenge the tobacco control measures in Australia).

292. *See* Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Award (July 8, 2016) (using the investor-state dispute settlement mechanism in the bilateral agreement between Switzerland and Uruguay to challenge the tobacco control measures in Uruguay).

293. *See* Eli Lilly & Co. v. Gov't of Can., ICSID Case No. UNCT/14/2, Final Award (Mar. 16, 2017) (utilizing Chapter Eleven of the North American Free Trade Agreement to seek compensation for the Canadian courts' invalidation of its patents on two hyperactivity drugs).

294. *See* Bridgestone Licensing Servs., Inc. v. Republic of Pan., ICSID Case No. ARB/16/34, Request for Arbitration (Oct. 7, 2016) (using the investor-state dispute settlement mechanism in the bilateral agreement between Panama and the United States to challenge the damage award granted by the Supreme Court of Panama in relation to the investor's action in opposing a trademark registration).

295. Yu, *Investment-Related Aspects*, *supra* note 288, at 831.

296. *See, e.g.*, FREDERICK M. ABBOTT ET AL., INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY 3 (2007) (stating that "the TRIPS Agreement represented

In the context of pharmaceutical products, the treatment of intellectual property rights as investments is particularly intuitive considering the heavy R&D expenditures and the pharmaceutical industry's longstanding emphasis on their investments. As Frederick Abbott observed:

> A patent is essentially a financial instrument that entitles its bearer to achieve greater than competitive market rates of return on investment. The Pharma companies are market-oriented enterprises that seek to maximize shareholder returns on investment. Pharma treats potential intrusion on the security of the patent and related regulatory support as a threat to return on investment. Pharma justifies its rent seeking as necessary to the funding of research and development for new medicines. . . .
>
> . . . .
>
> . . . The Pharma companies demand rules and enforcement that will protect their income streams, justifying a high return on investment as necessary to drug development.[297]

As if these inter-regime and cross-regime developments were not complicated enough, the increasing emphasis on data protection has created additional linkage between the protection of undisclosed test or other data for pharmaceutical and agrochemical products and other areas of data governance. Until such linkage arises, the protection of undisclosed test or other data for pharmaceutical and agrochemical products has remained a domain of its own. Article 39 is the only provision available in Section 7 of the TRIPS Agreement, distinct from the sections on copyright, patent, trademark, and other forms of intellectual property rights.[298] Nevertheless, some commentators have criticized the TRIPS negotiators for lumping Articles 39.2 and 39.3 in the same provision, considering the significant difference between trade secret protection and the protection of undisclosed test or other data.[299]

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a sea change in the international regulation of [intellectual property rights]"); WATAL, *supra* note 11, at 2 ("TRIPS is, by far, the most wide-ranging and far reaching international treaty on the subject of intellectual property to date and marks the most important milestone in the development of international law in this area."); Charles R. McManis, *Teaching Current Trends and Future Developments in Intellectual Property*, 52 ST. LOUIS U. L.J. 855, 856 (2008) (noting that "the field of international intellectual property law underwent a tectonic shift with the promulgation of the [TRIPS Agreement]").

297. Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, *in* NEGOTIATING HEALTH, *supra* note 41, at 27, 36.

298. *Compare* TRIPS Agreement, *supra* note 1, § 7, *with id.* §§ 1-6.

299. *Compare id.* art. 39.2, *with id.* art. 39.3; *see also* Sharon K. Sandeen, *The Limits of Trade Secret Law: Article 39 of the TRIPS Agreement and the Uniform Trade Secrets Act on Which It Is Based*, *in* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 537, 566 n.108 (Rochelle C. Dreyfuss & Katherine J. Strandburg

At first glance, undisclosed test or other data that are submitted for regulatory approval of pharmaceutical and agrochemical products are viewed as isolated personal data that are keyed to the development of specific products. However, as pharmaceutical and agrochemical industries continue to use big-data analytics in R&D and actively deploy sensors or other devices to capture test results, the line between test data and sensor-collected data is not as clear-cut as one imagines.[300] Thus, it is increasingly important to explore the protection and regulation of data as part of a holistic data governance regime.[301]

Consider, for instance, the European Commission's recent proposal to create a new "data producer's right" for nonpersonal, anonymized machine-generated data.[302] Traditionally, this proposed right would

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eds., 2011) (questioning "why the test data obligations of Art. 39(3) were placed in the same section as the obligations to protect undisclosed information").

300. Consultants from McKinsey noted the following possibilities:

> Advances in instrumentation through miniaturized biosensors and the evolution in smartphones and their apps are resulting in increasingly sophisticated health-measurement devices. Pharmaceutical companies can deploy smart devices to gather large quantities of real-world data not previously available to scientists. Remote monitoring of patients through sensors and devices represents an immense opportunity. This kind of data could be used to facilitate R&D, analyze drug efficacy, enhance future drug sales, and create new economic models that combine the provision of drugs and services.
>
> Remote-monitoring devices can also add value by increasing patients' adherence to their prescriptions. Examples of devices that are under development include smart pills that can release drugs and relay patient data, as well as smart bottles that help track usage. Technology and mobile providers are offering services such as data feeds, tracking, and analysis to complement medical devices. These devices and services, combined with in-home visits, have the potential to decrease health-care costs through shortened hospital stays and earlier identification of health issues.

Cattell et al., *supra* note 240; *see also* HOLMES, *supra* note 241, at 68-69 (discussing the use of sensor data in the health context, such as those relating to magnetic resonance imaging scans and wearable devices).

301. *See* Peter K. Yu, *Data Producer's Right and the Protection of Machine-Generated Data*, 93 TUL. L. REV. 859, 889-92 (2019) [hereinafter Yu, *Data Producer's Right*].

302. *Commission Communication on "Building a European Data Economy,"* COM(2017) 9 final (Jan. 10, 2017), at 13 [hereinafter *Commission Communication*]. As the European Commission explained:

> Machine-generated data is created without the direct intervention of a human by computer processes, applications or services, or by sensors processing information received from equipment, software or machinery, whether virtual or real.
>
> Machine-generated data can be personal or non-personal in nature. Where machine-generated data allows the identification of a natural person, it qualifies as personal data with the consequence that all the rules on personal data apply until such data has been fully anonymised (e.g. location data of mobile applications).

not have affected the protections under Article 39.3 of the TRIPS Agreement.[303] Nevertheless, if sensors are to be used to capture the motion of patients, or if wearables are deployed to measure the conditions of test subjects,[304] the proposed data producer's right can be implicated in the R&D process,[305] especially when the test results have been sufficiently anonymized.[306] Whether the rights implicated in this

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Id. at 9. *See generally* Yu, *Data Producer's Right*, *supra* note 301 (providing a critique of the proposed data producer's right).

303. TRIPS Agreement, *supra* note 1, art. 39.3.

304. As a McKinsey report stated:

> [A key] clinical big data lever is collecting data from remote patient monitoring for chronically ill patients and analyzing the resulting data to monitor adherence (determining if patients are actually doing what was prescribed) and to improve future drug and treatment options. An estimated 150 million patients in the United States in 2010 were chronically ill with diseases such as diabetes, congestive heart failure, and hypertension, and they accounted for more than 80 percent of health system costs that year. Remote patient monitoring systems can be highly useful for treating such patients. The systems include devices that monitor heart conditions, send information about blood-sugar levels, transmit feedback from caregivers, and even include "chip-on-a-pill" technology—pharmaceuticals that act as instruments to report when they are ingested by a patient—that feeds data in near real time to electronic medical record databases. Simply alerting a physician that a congestive heart failure patient is gaining weight because of water retention can prevent an emergency hospitalization. More generally, the use of data from remote monitoring systems can reduce patient in-hospital bed days, cut emergency department visits, improve the targeting of nursing home care and outpatient physician appointments, and reduce long-term health complications.

MANYIKA ET AL., *supra* note 246, at 45-46.

305. As the McKinsey report continued:

> Another promising big data innovation that could produce value in the R&D arena is the analysis of emerging large datasets (e.g., genome data) to improve R&D productivity and develop personalized medicine. The objective of this lever is to examine the relationships among genetic variation, predisposition for specific diseases, and specific drug responses and then to account for the genetic variability of individuals in the drug development process.

Id. at 48.

306. As the European Commission explained in relation to the proposed data producer's right:

> Where personal data are concerned, the individual will retain his right to withdraw his consent at any time after authorising the use. Personal data would need to be rendered anonymous in such a manner that the individual is not or no longer identifiable, before its further use may be authorised by the other party. Indeed, the GDPR [EU General Data Protection Regulation] continues to apply to any personal data (whether machine generated or otherwise) until that data has been anonymised.

Commission Communication, *supra* note 302, at 13; *see also* Yu, *Data Producer's Right*, *supra* note 301, at 920 ("GDPR and other privacy laws cover personal data, while the proposed data producer's right focuses on non-personal, anonymized machine-generated data.").

process should be governed by rules in the intellectual property, trade, privacy, or other areas remains difficult to determine.

In sum, as the protection in one international regime spills over into the protection in another, policymakers and commentators need to be ready to address the complications created when two or more regimes overlap. It is unclear whether such overlap will strengthen or weaken the protection of undisclosed test or other data—or, for our purposes, whether such overlap will advance or stifle the TRIPS harmonization project. It is nevertheless quite certain that the overlap will complicate future negotiations in this area. The more complicated the negotiations are, the less well-equipped trade negotiators will be to handle all of the negotiations involved. For a harmonization project that has been driven heavily by trade negotiators, the complications caused by increasing spillovers of regulatory standards from overlapping international regimes is indeed a major concern.

V. LESSONS

Thus far, this Article has explored the contestations between developed and developing countries over the international minimum standards for protecting undisclosed test or other data for pharmaceutical and agrochemical products.[307] The Article has also identified three additional challenges that could affect the development of new international intellectual property norms.[308] This Part turns to the various lessons one can glean from studying the past twenty-five years of TRIPS and TRIPS-plus developments surrounding the protection of undisclosed test or other data for pharmaceutical and agrochemical products.

First, although voluminous literature has already shown that the TRIPS Agreement and TRIPS-plus bilateral, regional, and plurilateral agreements have ratcheted up the standards for intellectual property protection,[309] one should be cautious when evaluating the successes and limitations of the TRIPS harmonization project.[310] Although Article 39.3 of the TRIPS Agreement successfully introduced new international norms concerning the protection of undisclosed test or other data, one could locate significant limits to this harmonization project

307. *See* discussion *supra* Parts II and III.

308. *See* discussion *supra* Part IV.

309. *See generally* authorities cited in *supra* note 9.

310. *See Susy Frankel*, *The Fusion of Intellectual Property and Trade*, *in* FRAMING INTELLECTUAL PROPERTY LAW IN THE 21ST CENTURY: INTEGRATING INCENTIVES, TRADE, DEVELOPMENT, CULTURE, AND HUMAN RIGHTS 89, 102 (Rochelle Cooper Dreyfuss & Elizabeth Siew-Kuan Ng eds., 2018) ("TRIPS did not harmonize and, as its negotiating history shows, could not have harmonized many intellectual property standards.").

based on the limited language in Article 39.3, the WTO dispute between Argentina and the United States, and the continuous contestations over the appropriate international intellectual property standards both inside and outside the WTO.

Second, from the negotiation of the TRIPS Agreement to the development of TRIPS-plus bilateral, regional, and plurilateral agreements, power politics has heavily driven the negotiating process. The compromises struck in the development of Article 39.3 vividly show the significant divide between developed and developing countries.[311] The continuous contestations over international minimum standards in TRIPS-plus agreements also reveal the different positions taken by key *demandeurs* in the developed world—notably the European Union, Japan, and the United States. Indeed, the negotiating history surrounding the increased protection of undisclosed test or other data for pharmaceutical and agrochemical products is highly interesting because it has been affected by not only the traditional North-South divide but also the strong disagreements between developed countries.[312] Until these powerful countries come together to present a united negotiating front—similar to what they did at the TRIPS negotiations[313]—they will have tremendous difficulty in convincing developing countries to offer stronger protection in this area.

Third, because of the continuous contestations within and outside the WTO, developing countries still retain considerable flexibilities concerning the protection of test or other data for pharmaceutical and agrochemical products. There are two different types of flexibilities:

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311. As Jayashree Watal recounted:

> [O]n a lot of issues, including in the politically sensitive areas such as patents, trade secrets and test data protection, there were North–North differences that persisted until the end. Developing countries such as India participated in negotiating each provision of the TRIPS Agreement, contrary to certain accounts. They seized opportunities that were offered on account of these intra-North differences, wherever they became aware of such discord.

Jayashree Watal, *Patents: An Indian Perspective*, *in* MAKING OF THE TRIPS AGREEMENT, *supra* note 109, at 295, 301.

312. *See* Meir Perez Pugatch, *Intellectual Property, Data Exclusivity, Innovation and Market Access*, *in* NEGOTIATING HEALTH, *supra* note 41, at 97, 102-10 (distinguishing between the U.S., EU, and Canadian models for protecting undisclosed test or other data for pharmaceutical and agrochemical products).

313. *See* WATAL, *supra* note 11, at 44 (noting that the European Communities, Japan, and the United States managed to coordinate their positions "through discussions and negotiations amongst relevant segments of industry and government aided by [intellectual property] specialists, at the preparatory stages as well as during the Uruguay Round"); Yu, *Currents and Crosscurrents*, *supra* note 8, at 363 ("Although the initial positions and national laws of the European Community, Japan, and the United States differ significantly, they managed to present 'fairly coordinated positions' during the negotiation process." (quoting WATAL, *supra* note 11, at 44)).

consensus-based flexibilities and contestation-driven flexibilities. The built-in flexibilities explicitly provided by Article 39.3 of the TRIPS Agreement belong to the first type, while the considerable variations in the different regional and plurilateral agreements concerning the protection of undisclosed test or other data for pharmaceutical and agrochemical products belong to the second type. As Part III noted, the TPP, the RCEP, and the USMCA all feature TRIPS-plus standards for the protection of these data.[314] Nevertheless, the standards in these three agreements vary considerably, with the USMCA being the strongest and the RCEP being the weakest.[315] To a large extent, the variations in these agreements provide developing countries with the much-needed "wiggle room"[316] to develop their laws and policies regarding the protection of undisclosed test or other data for pharmaceutical and agrochemical products. Thus, even though TRIPS-plus bilateral, regional, and plurilateral agreements have eroded the consensus-based flexibilities provided by the TRIPS Agreement, developing countries continue to benefit from contestation-driven flexibilities.

Fourth, although commentators often describe developing countries as if they were a homogenous group, the slowly changing policy position taken by China suggests the increased complexity concerning positions taken by developing countries.[317] To be sure, many international intellectual property negotiations are still conducted along the North-South fault lines.[318] Nevertheless, the traditional divide between developed and developing countries does not fully capture the interests and aspirations of the latter group of countries. Indeed, as noted by commentators, myself included,[319] there is a growing need to

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314. *See* discussion *supra* Part III.

315. *Compare* USMCA, *supra* note 16, arts. 20.45, 20.48, 20.49, *with* TPP Agreement, *supra* note 12, arts. 18.47, 18.50, 18.51, *and* October 15 Draft, *supra* note 188, art. 5.16.

316. *See* J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 28 (1997) (contending that "the TRIPS Agreement leaves developing countries ample 'wiggle room' in which to implement national policies favoring the public interest in free competition").

317. *See* discussion *supra* Section IV.B (discussing China's innovative turn and changing position in the pharmaceutical area).

318. For the Author's discussions of the positions taken by developing countries in international intellectual property regime, see generally Peter K. Yu, *Intellectual Property Negotiations, the BRICS Factor and the Changing North–South Debate*, *in* THE BRICS-LAWYERS' GUIDE TO GLOBAL COOPERATION 148 (Rostam J. Neuwirth et al. eds., 2017); Peter K. Yu, *TRIPS Wars: Developing Countries Strike Back*, *in* FLASHPOINTS: CHANGING PARADIGMS IN INTELLECTUAL PROPERTY AND TECHNOLOGY LAW (Alexandra George ed., forthcoming 2019); Yu, *TRIPS Game*, *supra* note 29; Yu, *TRIPS and Its Discontents*, *supra* note 6.

319. *See generally* Peter K. Yu, *The Middle Intellectual Property Powers*, *in* LAW AND DEVELOPMENT OF MIDDLE-INCOME COUNTRIES: AVOIDING THE MIDDLE-INCOME TRAP 84 (Randall Peerenboom & Tom Ginsburg eds., 2014) (discussing the complications created by emerging intellectual property powers).

develop new taxonomies to describe the different, and at times complex, positions taken by China, India, and other emerging countries.[320] For example, one could replace developed and developing countries with "high-income, middle-income, and low-income" countries.[321] Alternatively, countries could be grouped together based on such factors as technological proficiency[322] and patent intensity.[323]

Fifth, there is an inevitable cat-and-mouse chase between international treaties and technological developments. The complications posed by the arrival of big-data analytics and the increased importance and popularity of biologics and personalized medicines aptly illustrate the considerable difficulties in, if not impossibility of, anticipating future technological challenges. It is telling that the TPP intellectual property chapter includes a review clause that "[r]ecogni[zes] 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."[324] Indeed, shortly after the adoption of the TRIPS Agreement, some commentators took the position that the Agreement was obsolete upon arrival.[325] While limited cover-

320. *See* Basheer & Primi, *supra* note 4 (noting that countries can be technologically proficient even though they may not be economically developed, especially on a per capita basis); Daniel Benoliel & Bruno Salama, *Towards an Intellectual Property Bargaining Theory: The Post-WTO Era*, 32 U. PA. J. INT'L L. 265, 271 (2010) (noting the need to separate countries based on their bargaining power within the international intellectual property regime); Bradly Condon & Tapen Sinha, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, 26 NW. J. INT'L L. & BUS. 1, 41 (2005) (noting that the U.N. classification of developed, developing, and least developed countries "is an inappropriate basis for achieving an equitable balance between the rights of patent owners and users").

321. *See* Peter K. Yu, *Crossfertilizing ISDS with TRIPS*, 49 LOY. U. CHI. L.J. 321, 345 (2017) (using the trichotomy of "high-income, middle-income, and low-income" countries to replace the dichotomy of developed and developing countries).

322. *See* Basheer & Primi, *supra* note 4 (calling for greater differentiation of developing countries based on their technological proficiencies).

323. *See generally* DANIEL BENOLIEL, PATENT INTENSITY AND ECONOMIC GROWTH (2017) (providing an empirically based alternative conceptual framework for grouping countries together for policy analysis).

324. TPP Agreement, *supra* note 12, art. 18.51.3.

325. As Marci Hamilton aptly observed:

> Despite its broad sweep and its unstated aspirations, TRIPS arrives on the scene already outdated. TRIPS reached fruition at the same time that the on-line era became irrevocable. Yet it makes no concession, not even a nod, to the fact that a significant portion of the international intellectual property market will soon be conducted on-line.

Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective*, 29 VAND. J. TRANSNAT'L L. 613, 614-15 (1996). Likewise, Jerome Reichman declared:

> [The principal weakness of the TRIPS Agreement] stems from the drafters' technical inability and political reluctance to address the problems facing innovators

age of Internet-related issues provides a good indication of its obsolescence,[326] the TRIPS Agreement's inability to capture the latest innovations in the biotechnology area foreshadows many of the challenges we see today in the area of biologics.[327]

Finally, given the ubiquity of technology-related issues and the growing attention devoted to intellectual property law and policy, standards in the international intellectual property regime are increasingly linked to—if not affected by—developments and expectations in other international regimes. John Braithwaite, Peter Drahos, and Laurence Helfer were right to underscore the active forum-shifting or regime-shifting activities in the international arena.[328] Such ac-

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> and investors at work on important new technologies in an Age of Information. The drafters' decision to stuff these new technologies into the overworked and increasingly obsolete patent and copyright paradigms simply ignores the systemic contradictions and economic disutilities this same approach was already generating in the domestic intellectual property systems.

J.H. Reichman, *The Know-How Gap in the TRIPS Agreement: Why Software Fared Badly, and What Are the Solutions*, 17 HASTINGS COMM. & ENT. L.J. 763, 766 (1995) (footnote omitted).

326. *See* Hamilton, *supra* note 325, at 615 (criticizing the TRIPS Agreement for "mak[ing] no concession, not even a nod, to the fact that a significant portion of the international intellectual property market will soon be conducted on-line"); Peter K. Yu, *Teaching International Intellectual Property Law*, 52 ST. LOUIS U. L.J. 923, 933 (2008) ("The drafters [of the TRIPS Agreement] . . . did not anticipate all of the latest technological changes. A good example of these unanticipated changes concerns the technological change brought about by the information revolution."); Yu, *Achilles' Heel*, *supra* note 143, at 502-03 (discussing the technological challenges that have prevented the TRIPS Agreement from providing effective global enforcement of intellectual property rights).

327. *See* Peter K. Yu, *Enforcement, Enforcement, What Enforcement?*, 52 IDEA 239, 247-48 (2012) ("Although the biotechnology revolution had already raised many difficult policy and ethical questions by the mid-1980s, Article 27 provides only very limited coverage of biotechnology-related issues.").

328. For excellent discussions of the regime-shifting phenomenon, see generally JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 564-71 (2000); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1 (2004). As Professors Braithwaite and Drahos explained:

> International forum-shifting was not an important strategy prior to the Second World War, when the number of international fora was so small as to afford little choice. It became an important strategy for the first time during the era of US hegemony. The US state in fact translated its "national legal pastime" of forum-shifting into the realm of international regulatory contests. When it is staring at defeat on a given regulatory agenda in a given international forum it shifts that agenda to another forum, or simply abandons that forum. Part of its thinking behind abandonment is that the abandoned international organization will be shocked into a more compliant mode of behaviour, endeavouring to woo back the world's most powerful state (and its financial contributions) with more favourable policies and attitudes . . . . On other occasions forum-shifting is used to run a parallel agenda in two international fora. Here the strategy is to cast both

tivities have led to what Christopher May described as "forum proliferation."[329] Now that so many international fora have been created, the overlap between them is inevitable, especially when their coverage expands. In fact, the more overlap there is between these different international fora, the more complicated the developments will be. After all, many international regimes carry with them different players, structures, language, culture, and values. The questions explored in relation to intellectual property law are not always the same as those that are being asked in the health, trade, or investment context.[330] The answers to these questions are also likely to be significantly different.[331]

VI. CONCLUSION

The TRIPS Agreement was adopted with the WTO's formation in Marrakesh in April 1994. Although commentators have widely recognized the Agreement's ability to impose on developing countries high standards for intellectual property protection and enforcement, a close

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fora in the role of warring suitors, making each strive to do better than the other in terms of fulfilling the regulatory desires of the US.

BRAITHWAITE & DRAHOS, *supra*, at 564; *see also* Yu, *Currents and Crosscurrents*, *supra* note 8, at 408-16 (discussing regime-shifting activities).

329. CHRISTOPHER MAY, THE WORLD INTELLECTUAL PROPERTY ORGANIZATION: RESURGENCE AND THE DEVELOPMENT AGENDA 66 (2007).

330. *See* Yu, *Investment-Related Aspects*, *supra* note 288, at 857 ("Within the intellectual property field, there is . . . a considerable concern that [investor-state dispute settlement] arbitrators would subscribe to a narrow view of intellectual property rights. In doing so, they may focus primarily on the protection levels without adequately considering the corresponding limitations or exceptions."); Yu, *Reconceptualizing Intellectual Property Interests*, *supra* note 118, at 1137 ("Today, the development of intellectual property laws and policies is no longer just about intellectual creations; it has, indeed, affected many areas that are related to other human rights, including agriculture, health, the environment, education, culture, free speech, privacy, and democracy."); Sisule F. Musungu, *Rethinking Innovation, Development and Intellectual Property in the UN: WIPO and Beyond* 4-5 (Quaker Int'l Affairs Programme, TRIPS Issues Paper No. 5, 2005) ("So far the only widely accepted notion has been that intellectual property is trade-related, justifying the TRIPS Agreement in the WTO but not the notion that intellectual property rules are also education-related, health-related, defence-related and environment-related and so forth.").

331. *See* Daniel J. Gervais, *How Intellectual Property and Human Rights[] Can Live Together: An Updated Perspective*, *in* INTELLECTUAL PROPERTY LAW AND HUMAN RIGHTS 3, 12 (Paul L.C. Torremans ed., 3d ed. 2015) ("Exceptions to copyright are seen through a trade-related effects-based prism."); Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 914–15 (2003) (expressing disappointment that WTO panels, despite focusing on the purpose and objective of the TRIPS Agreement and the context of the negotiations, "have interpreted the provisions almost solely in light of the economic expectations of the private right holders"); Yu, *Nonmultilateral Era*, *supra* note 118, at 1083-84 (noting that the views taken by intellectual property rights holders and their supportive governments "are often colored by the trade-based—and at times, trade-only—approach developed through the founding of the WTO and the adoption of the TRIPS Agreement").

scrutiny of developments in the area of test or other data for pharmaceutical and agrochemical products suggests considerable limits to the TRIPS harmonization project. If we are to take stock of the developments in the TRIPS arena, we need to be conscious of both the successes and weaknesses of this project.

Utilizing the protection of undisclosed test or other data for pharmaceutical and agrochemical products as a case study, this Article assesses whether the TRIPS Agreement and TRIPS-plus bilateral, regional, and plurilateral agreements have succeeded in facilitating harmonization of the international minimum standards for the protection and enforcement of intellectual property rights. The findings show active contestations between developed and developing countries that have been further affected by changing technological developments, shifting intellectual property politics, and increasing spillovers of regulatory standards from other international regimes. Although greater harmonization of international intellectual property norms has been justified by such benefits as efficiency, consistency, predictability, and coherence, there is sufficient evidence to show that such harmonization remains a work-in-progress—and for good reasons.

It is hard to believe that the WTO and its TRIPS Agreement have already been around for twenty-five years. Notwithstanding their developments for a quarter-century, the Agreement remains fairly young, and its ability to harmonize international minimum standards has yet to reach the level of earlier and more established international intellectual property agreements.[332] It remains to be seen whether the TRIPS Agreement will eventually succeed in harmonizing the international standards for protecting undisclosed test or other data for pharmaceutical and agrochemical products, but twenty-five years is simply not enough for us to see the completion of the TRIPS harmonization project.

332. Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 25 U.S.T. 1341, 828 U.N.T.S. 221 (revised at Paris July 24, 1971); Madrid Agreement Concerning the International Registration of Marks, Apr. 14, 1891, 828 U.N.T.S. 389 (revised at Stockholm July 14, 1967); Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1538, 828 U.N.T.S. 305 (revised at Stockholm July 14, 1967).