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# Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals

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## DATA EXCLUSIVITIES IN THE AGE OF BIG DATA, BIOLOGICS, AND PLURILATERALS

*Peter K. Yu\**

### INTRODUCTION

The past decade has seen many new developments impacting the intellectual property system. The introduction of big data analytics has transformed the fields of biotechnology and bioinformatics while ushering in major advances in drug development, clinical practices, and medical financing.<sup>1</sup> The arrival of biologics and personalized medicines has also revolutionized the healthcare and pharmaceutical industries. In addition, the emergence of bilateral, regional, and plurilateral trade agreements have raised serious, and at times difficult, questions concerning the evolution of domestic and international intellectual property standards.

One topic linking all three developments together concerns the establishment of international standards to protect clinical trial data that have been submitted to regulatory authorities for the marketing approval of pharmaceutical products. During the negotiations for the Trans-Pacific Partnership (TPP),<sup>2</sup> for example, the protection of clinical trial data submitted for the marketing approval of biologics was highly contentious.<sup>3</sup> Although the United States' withdrawal in January 2017<sup>4</sup> has since placed the TPP Agreement and its data exclusivity provisions for pharmaceuticals and biologics on life support,<sup>5</sup> the debate on the protection of clinical trial data will continue and will emerge in future bilateral, regional, and plurilateral trade negotiations, including the renegotiations on the North American Free Trade Agreement (NAFTA).<sup>6</sup>

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<sup>1</sup> See Ryan Abbott, *Big Data and Pharmacovigilance: Using Health Information Exchanges to Revolutionize Drug Safety*, 99 IOWA L. REV. 225, 227 (2013).

<sup>2</sup> Trans-Pacific Partnership Agreement, Feb. 4, 2016, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> [hereinafter TPP Agreement].

<sup>3</sup> See 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/>.

<sup>4</sup> See Presidential Memorandum Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement, 82 Fed. Reg. 8497 (Jan. 23, 2017) [hereinafter Presidential Memorandum].

<sup>5</sup> See generally 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).

<sup>6</sup> North American Free Trade Agreement, Can.-Mex.-U.S., Annex 2106, Dec. 17, 1992, 32 I.L.M. 289, 702 [hereinafter NAFTA].

Part I of this Article reviews the protection of clinical trial data under Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>7</sup> (TRIPS Agreement) of the World Trade Organization (WTO). Even though the provision covers both pharmaceutical and agricultural chemical products, this Article focuses only on the former. Part II examines the additional protection clinical trial data have received through TRIPS-plus bilateral, regional, and plurilateral trade agreements. Part III outlines five specific recommendations to help advance the debate on such protection in the age of big data, biologics, and plurilateral trade agreements.

## I. TRIPS AGREEMENT

Until the adoption of the TRIPS Agreement, undisclosed information “has never been the subject of any multilateral agreement.”<sup>8</sup> 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.<sup>9</sup> Such submission is important because the collected data will help authorities evaluate the products’ safety and efficacy. Specifically, Article 39.3 provides:

Members, when requiring, as a condition of approving the marketing of pharmaceutical . . . 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.<sup>10</sup>

To a large extent, this provision reflects the difficult compromise struck between developed and developing countries during the TRIPS negotiations. For countries that have a strong pharmaceutical industry, greater protection of clinical trial data will provide additional incentives for research and development while increasing the countries’ competitive and comparative advantage.<sup>11</sup> For countries without a strong pharmaceutical industry, however, greater protection of such data will increase healthcare costs, reduce access to medicines, and delay market entry of generic drugs.<sup>12</sup> Such protection will not only jeopardize public health—at both the domestic and global levels—but will also raise ethical questions about unnecessary duplicative testing.<sup>13</sup>

Since the adoption of Article 39.3 of the TRIPS Agreement, policymakers and commentators in, or sympathetic to, developing countries have highlighted five specific concerns. The first concern relates to the regulatory authorities’ ability to rely on previously submitted clinical trial data to grant marketing approval of follow-on drugs. Such reliance occurs when these

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<sup>7</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

<sup>8</sup> JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 4 (2001).

<sup>9</sup> TRIPS Agreement, *supra* note 7, art. 39.3.

<sup>10</sup> *Id.*

<sup>11</sup> 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, 12–15 (2003); Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 784 (2010) [hereinafter Yu, *Political Economy*].

<sup>12</sup> See Yu, *Political Economy*, *supra* note 11, at 784–85.

<sup>13</sup> See *id.* at 785–86; Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 81, 93 (Pedro Roffe et al. eds., 2006) [hereinafter NEGOTIATING HEALTH]; 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, 475–76 (2004).

authorities approve new drugs based on evidence provided by bioequivalence studies.<sup>14</sup> Unlike NAFTA, which will be discussed below, the TRIPS Agreement does not include explicit language mentioning data reliance.<sup>15</sup> A review of the 1990 Brussels draft of the TRIPS Agreement shows that the final text removed 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 origination 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.<sup>16</sup>

Drawing on this important piece of negotiating history—an interpretive approach supported by the Vienna Convention on the Law of Treaties<sup>17</sup>—it is quite clear that the TRIPS negotiating parties did not achieve consensus over the data reliance issue.<sup>18</sup> Indeed, the removal of the Brussels language strongly supports the view that the TRIPS Agreement does not prohibit regulatory authorities from relying on previously submitted clinical trial 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 unbargained-for trade concessions beyond what was agreed in TRIPS without any legal foundation whatsoever.<sup>19</sup>

Moreover, the use of bioequivalence studies to grant marketing approvals does not always require the use or disclosure of previously submitted clinical trial 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) . . . .<sup>20</sup>

This observation is particularly important when one takes into account the need of the big data environment. In this environment, what is highly valuable are the collected clinical trial data and

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<sup>14</sup> See, e.g., 21 U.S.C. § 355(j)(8)(B) (2012).

<sup>15</sup> Compare TRIPS Agreement, *supra* note 7, art. 39.3, with NAFTA, *supra* note 6, art. 1711.6.

<sup>16</sup> UNCTAD-ICTSD PROJECT ON INTELLECTUAL PROPERTY RIGHTS AND SUSTAINABLE DEVELOPMENT, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 525 (2005) [hereinafter TRIPS RESOURCE BOOK].

<sup>17</sup> 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) (including “the preparatory work of the treaty and the circumstances of its conclusion” as “supplementary means of interpretation”).

<sup>18</sup> Compare Fellmeth, *supra* note 13, at 454–60, with Skillington & Solovy, *supra* note 11, at 15–21.

<sup>19</sup> Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods*, in NEGOTIATING HEALTH, *supra* note 13, at 133, 140.

<sup>20</sup> *Id.* at 142.

their ability to provide a large and comprehensive dataset,<sup>21</sup> not the specific health and safety outcome 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 clinical trial data themselves or secure a license to use the originators' data.

The second concern pertains to the continuation of data exclusivity protection even when the relevant drug is no longer protected by a patent, such as when the drug is in the public domain or when the granted patent has been subsequently invalidated.<sup>22</sup> To be sure, the term of data exclusivity protection is usually shorter than the term of patent protection. In most circumstances, the protection of clinical trial 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 pharmaceuticals to about fourteen years,<sup>23</sup> that period is still much longer than the usual five-year period of data exclusivity for pharmaceuticals.<sup>24</sup>

For pharmaceuticals no longer protected by patents, however, data exclusivity laws could provide substitutional protection. Although Article 39.3 conditions protection on the existence of "new chemical entities," the TRIPS Agreement does not require the relevant entities to meet the novelty standard commonly found in patent law.<sup>25</sup> Instead, it provides WTO members with wide discretion to set their own standards. For instance, policymakers and commentators in developed countries have widely considered the term "new chemical entities" to require only the lack of prior regulatory approval of the pharmaceutical products at issue.<sup>26</sup> In the past decade, the United States and other WTO members have actively sought TRIPS-plus agreements to clarify the definition of newness.<sup>27</sup> 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."<sup>28</sup>

The third concern involves the use of compulsory licenses. Article 31 of the TRIPS Agreement clearly delineates the complex conditions under which these licenses are to be issued for patented products.<sup>29</sup> Article 31*bis*, which recently entered into force, also extends the compulsory licensing arrangement to countries with insufficient or no drug manufacturing capacity.<sup>30</sup> Unlike those two provisions, however, Article 39.3 is not subject to the compulsory licensing arrangement provided in the TRIPS Agreement. The lack of coverage has therefore raised an interesting question concerning whether WTO members can utilize the clinical trial data

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<sup>21</sup> See VIKTOR MAYER-SCHÖNBERGER & KENNETH CUKIER, *BIG DATA: A REVOLUTION THAT WILL TRANSFORM HOW WE LIVE, WORK AND THINK* 19–31, 98–122 (2014).

<sup>22</sup> See Srividhya Ragavan, *Data Exclusivity: A Tool to Sustain Market Monopoly*, 8 JINDAL GLOBAL L. REV. 241, 252–53 (2017).

<sup>23</sup> See Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 72 n.24 (2005).

<sup>24</sup> See NAFTA, *supra* note 6, art. 1711.6; TPP Agreement, *supra* note 2, art. 18.50.

<sup>25</sup> See CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 378 (2007); TRIPS RESOURCE BOOK, *supra* note 16, at 530; Ragavan, *supra* note 22, at 252–54.

<sup>26</sup> See Skillington & Solovy, *supra* note 11, at 25–28; see also 21 C.F.R. § 314.108(b)(2) (2017).

<sup>27</sup> See TPP Agreement, *supra* note 2, arts. 18.47.3, 18.52.

<sup>28</sup> *Id.* art. 18.52 (footnote omitted).

<sup>29</sup> TRIPS Agreement, *supra* note 7, art. 31.

<sup>30</sup> General Council, *Amendment of the TRIPS Agreement*, WTO Doc. WT/L/641 (Dec. 8, 2005). The amendment was adopted in January 2017 after it had been opened for ratification for more than a decade. See 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://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm).

submitted to regulatory authorities for the purposes of granting marketing approval of pharmaceuticals that are to be issued under compulsory licenses.<sup>31</sup> An additional question concerns whether data exclusivity protection can be waived upon the issuance of such licenses.<sup>32</sup>

The fourth concern emerged with the arrival of biologics. Commentators have noted the challenge of obtaining sufficient protection for these products through the patent system. Because biologics involve biological materials, their protection often have to rely on process patents, rather than product patents.<sup>33</sup> Moreover, Article 39.3 does not grant protection to biologics because those products are not considered “new chemical entities” within the meaning of the TRIPS Agreement.<sup>34</sup> The insufficient protection provided by the TRIPS regime indeed explains why Europe, Japan, and the United States have eagerly pushed for specific provisions relating to biologics in bilateral, regional, and plurilateral trade negotiations.<sup>35</sup>

Finally, many 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. Examples of TRIPS-plus standards that the United States has pushed through bilateral, regional, and plurilateral trade negotiations are the increase in patent standards, the extension of the patent term due to regulatory delay, the protection granted to new uses (or second indications) of known chemical compounds, market or data exclusivity for clinical trial data, the linkage of registration to the drug’s patent status, and the strengthening of enforcement relating to seizure of in-transit drugs.<sup>36</sup> While the introduction of one of these higher standards will be challenging enough for a developing country, the simultaneous introduction of multiple standards can be highly detrimental.

## II. TRIPS-PLUS AGREEMENTS

Although the TRIPS Agreement does not cover data reliance, Article 1711.6 of NAFTA 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 a reasonable period of time after their submission.”<sup>37</sup> Unlike the TRIPS Agreement, which does not provide any guidance on minimum duration, Article 1711.6 of NAFTA 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,

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<sup>31</sup> See Correa, *supra* note 13, at 94; Robert Weissman, *Data Protection: Options for Implementation*, in NEGOTIATING HEALTH, *supra* note 13, at 151, 168–74.

<sup>32</sup> See Correa, *supra* note 13, at 94; Weissman, *supra* note 31, at 168–70.

<sup>33</sup> See W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 527 (2014); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1051 (2016); 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.

<sup>34</sup> See Ragavan, *supra* note 22, at 255–56.

<sup>35</sup> See, e.g., TPP Agreement, *supra* note 2, art. 18.51.

<sup>36</sup> See Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 868–69 (2007).

<sup>37</sup> NAFTA, *supra* note 6, art. 1711.6.

taking account of the nature of the data and the person's efforts and expenditures in producing them.<sup>38</sup>

Thus, even 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.

Building on NAFTA and the TRIPS Agreement, the new free trade agreements that the United States has established since the early 2000s have actively strengthened the protection of clinical trial data.<sup>39</sup> A case in point is Article 17.10 of the Australia-United States Free Trade Agreement.<sup>40</sup> Unlike NAFTA or the TRIPS Agreement, this provision does not focus on reliance, disclosure, or unfair commercial use. Instead, it requires signatories to provide a market exclusivity regime. Article 17.10.1(a) states:

[T]he Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for at least five years from the date of marketing approval by the Party.<sup>41</sup>

The distinction between market exclusivity and data exclusivity is noteworthy. While the former prevents the marketing of a new drug based on the utilization of or reliance on previously submitted clinical trial data, the latter prevents the utilization or reliance of those data during the exclusivity term. By the time that term is over, follow-on drug developers 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.<sup>42</sup>

In March 2010, the United States and its trading partners launched the TPP negotiations.<sup>43</sup> Included in Chapter 18 of the TPP Agreement are the provisions on clinical trial data that have been submitted for the marketing approval of pharmaceutical products.<sup>44</sup> Similar to what is found in recent U.S. free trade agreements, the TPP Agreement requires parties to establish a market exclusivity regime, with protection lasting for at least five years.<sup>45</sup> The Agreement also includes language offering protection to new clinical information<sup>46</sup> and to “new pharmaceutical products that contain a chemical entity that has not been previously approved” by regulatory authorities.<sup>47</sup>

In addition, Article 18.51 includes a highly controversial provision on biologics. Similar to the provision on pharmaceutical products, this provision requires the establishment of a market

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<sup>38</sup> *Id.*

<sup>39</sup> See Margo A. Bagley, *Patent Term Restoration and Non-Patent Exclusivity in the USA*, in PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW: A TRILATERAL PERSPECTIVE 137–40 (Josef Drexl & Nari Lee eds., 2013).

<sup>40</sup> Australia-United States Free Trade Agreement, Austl.-U.S., May 18, 2004, 118 Stat. 919.

<sup>41</sup> *Id.* art. 17.10.1(a).

<sup>42</sup> See Public Citizen, *Data Exclusivity in the Regional Comprehensive Economic Partnership (RCEP)* 3, [https://www.citizen.org/system/files/case\\_documents/rcep-data-exclusivity\\_0.pdf](https://www.citizen.org/system/files/case_documents/rcep-data-exclusivity_0.pdf) (last visited Feb. 28, 2018).

<sup>43</sup> Press Release, Office of the U.S. Trade Representative, USTR Begins TPP Talks in Australia (Mar. 15, 2010), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2010/march/ustr-begins-tpp-talks-australia>.

<sup>44</sup> TPP Agreement, *supra* note 2, art. 18.50.

<sup>45</sup> *Id.* art. 18.50.1(a).

<sup>46</sup> *Id.* art. 18.50.2(a).

<sup>47</sup> *Id.* art. 18.50.2(b).

exclusivity regime.<sup>48</sup> Although the United States initially pushed for twelve years of protection,<sup>49</sup> the TPP negotiating parties ended up with a compromise term of “at least eight years from the date of first marketing approval.”<sup>50</sup> That term is longer than the market exclusivity period for chemical drugs but shorter than the one for agricultural chemical products.<sup>51</sup> To strike a compromise between the significantly different positions taken by the 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 term.<sup>52</sup>

On February 4, 2017, the TPP Agreement was finally signed in Auckland, New Zealand.<sup>53</sup> Although the Obama administration considered the Agreement a “cardinal priority and a cornerstone of [its] Pivot to Asia,”<sup>54</sup> the Trump administration took a very different approach. On the first day of his first full week in the administration, President Donald Trump signed a memorandum directing the United States Trade Representative to “withdraw the United States as a signatory to the [TPP and] . . . from TPP negotiations.”<sup>55</sup>

Since the United States’ withdrawal, the eleven remaining TPP partners worked hard to resuscitate the Agreement. At a May 2017 APEC meeting in Hanoi, Vietnam, these partners reaffirmed their commitment to establishing the TPP and agreed to explore the development of a process to move the partnership forward even without the United States’ participation.<sup>56</sup> A few months later, these countries “agreed on the core elements of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).”<sup>57</sup> This transition instrument sought to “incorporate provisions of the TPP, with the exception of a limited set of provisions, which will be suspended.”<sup>58</sup>

On January 23, 2018, exactly a year after President Trump signed his controversial presidential memorandum, the CPTPP negotiations concluded in Tokyo, Japan.<sup>59</sup> The agreement was subsequently signed in Santiago, Chile, on March 8.<sup>60</sup> Despite this transition instrument, it

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<sup>48</sup> *Id.* art. 18.51.1(a).

<sup>49</sup> See Kilic & Pine, *supra* note 3; see also 42 U.S.C. § 262(k)(7)(A) (2012).

<sup>50</sup> TPP Agreement, *supra* note 2, art. 18.51.1(a).

<sup>51</sup> Compare *id.* with *id.* arts. 18.47.1, 18.50.1(a).

<sup>52</sup> *Id.* art. 18.51.1(b).

<sup>53</sup> 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>.

<sup>54</sup> KURT M. CAMPBELL, THE PIVOT: THE FUTURE OF AMERICAN STATECRAFT IN ASIA 268 (2016).

<sup>55</sup> Presidential Memorandum, *supra* note 4.

<sup>56</sup> See Associated Press, *Pacific Ministers Commit to Move Ahead with Pact Without US*, U.S. NEWS & WORLD REP. (May 21, 2017), <https://www.usnews.com/news/business/articles/2017-05-21/pacific-ministers-commit-to-move-ahead-with-pact-without-us>.

<sup>57</sup> *Trans-Pacific Partnership Ministerial Statement* ¶ 3, GLOBAL AFFAIRS CANADA, <http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ppp-ptp/statement-declaration.aspx> (last modified Nov. 11, 2017).

<sup>58</sup> *Id.*

<sup>59</sup> See *Statement by Minister of International Trade on Successful Conclusion of Comprehensive and Progressive Agreement for Trans-Pacific Partnership*, GLOBAL AFFAIRS CANADA (Jan. 23, 2018), [https://www.canada.ca/en/global-affairs/news/2018/01/statement\\_by\\_ministerofinternationaltradeonsuccessfulconclusiono.html](https://www.canada.ca/en/global-affairs/news/2018/01/statement_by_ministerofinternationaltradeonsuccessfulconclusiono.html).

<sup>60</sup> 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>.

remains unclear whether the United States will rejoin the TPP in the future.<sup>61</sup> Regardless of the U.S. position, however, the CPTPP will have very little impact on the protection of clinical trial data that have been submitted to regulatory authorities for the marketing approval of pharmaceuticals and biologics. 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 [Articles 18.50 and 18.51], until the Parties agree to end suspension of one or more of these provisions."<sup>62</sup>

While the original TPP negotiations were underway in the early 2010s, Australia, China, India, Japan, New Zealand, South Korea, and the ten members of the Association of Southeast Asian Nations (ASEAN) began negotiating an alternative regional pact known as the Regional Comprehensive Economic Partnership (RCEP).<sup>63</sup> Included in the proposed partnership agreement is an intellectual property chapter featuring the protection of clinical trial data.<sup>64</sup> Unlike the TPP Agreement, which has offered NAFTA-plus protection to these data, the RCEP Agreement retains mostly NAFTA standards.

Based on the October 15, 2015, draft leaked by Knowledge Ecology International, the data exclusivity provision was proposed by Japan and South Korea but opposed by the remaining parties.<sup>65</sup> Calling for protection that goes beyond the TRIPS requirements, the proposed Article 5.16 requires each Party to "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" at least five years.<sup>66</sup>

### III. RECOMMENDATIONS

In light of these many TRIPS-plus developments regarding the protection of clinical trial data, this Part outlines five specific recommendations to help advance the policy and scholarly debate in this area. The first recommendation concerns the need to recognize the limited scope of protection for clinical trial data under the TRIPS Agreement. Although the pharmaceutical industry and its supportive policymakers continue to insist that the TRIPS Agreement prohibits regulatory

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<sup>61</sup> See Adam Edelman, *Trump Says He Would Consider Trans-Pacific Partnership with "Better Deal,"* NBC NEWS (Jan. 25, 2018), <https://www.nbcnews.com/politics/donald-trump/trump-says-he-would-consider-trans-pacific-partnership-better-deal-n841046>.

<sup>62</sup> Comprehensive and Progressive Agreement for Trans-Pacific Partnership art. 2, Annex, Mar. 8, 2018, <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-concluded-but-not-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text/>.

<sup>63</sup> See *Joint Declaration on the Launch of Negotiations for the Regional Comprehensive Economic Partnership* (Nov. 20, 2012), <http://dfat.gov.au/trade/agreements/rcep/news/Documents/joint-declaration-on-the-launch-of-negotiations-for-the-regional-comprehensive-economic-partnership.pdf>. For the Author's discussions of the RCEP negotiations, see Peter K. Yu, *TPP, RCEP, and the Crossvergence of Asian Intellectual Property Standards*, in GOVERNING SCIENCE AND TECHNOLOGY UNDER THE INTERNATIONAL ECONOMIC ORDER: REGULATORY DIVERGENCE AND CONVERGENCE IN THE AGE OF MEGAREGIONALS 277 (Peng Shin-yi et al. eds., 2018); and Peter K. Yu, *TPP, RCEP and the Future of Copyright Normsetting in the Asia-Pacific*, in MAKING COPYRIGHT WORK FOR THE ASIAN PACIFIC? JUXTAPOSING HARMONISATION WITH FLEXIBILITY (Susan Corbett & Jessica Lai eds., forthcoming 2018); and Peter K. Yu, *The RCEP and Trans-Pacific Intellectual Property Norms*, 50 VAND. J. TRANSNAT'L L. 673 (2017).

<sup>64</sup> See *Single Working Document on the Intellectual Property Chapter, Regional Comprehensive Economic Partnership (RCEP) Free Trade Agreement*, KNOWLEDGE ECOLOGY INT'L, <http://keionline.org/sites/default/files/RCEP-IP-Chapter-15October2015.docx> (last visited Mar. 1, 2018).

<sup>65</sup> *Id.* art. 5.16.

<sup>66</sup> *Id.*

authorities from relying on previously submitted clinical trial data,<sup>67</sup> the removal of the language in the Brussels draft provides strong evidence that no consensus on such reliance existed among TRIPS negotiators. Even if policymakers and commentators remain reluctant to accept the TRIPS Agreement's lack of coverage for data reliance—a view the Author holds—they should not waste time and effort rehashing the debate about whether the TRIPS Agreement has already offered some TRIPS-plus protections. Instead, they should focus their efforts on developing protection for clinical trial data in the post-TRIPS environment.

The second recommendation relates to the danger of overgeneralization in the intellectual property area. In assessing whether to grant new rights or strengthen existing ones, policymakers and commentators should avoid lumping data exclusivity protection with patents or other forms of intellectual property rights. The nature of, and justification for, each disparate form of intellectual property right is simply different.<sup>68</sup>

Thus far, the pharmaceutical industry has pushed aggressively for stronger data exclusivity laws to compensate for weak patent protection in foreign countries. For this industry, the protection of clinical trial data is just part of a multi-layered protection package available to its products. Nevertheless, policymakers and commentators should carefully consider the nature of, and justification for, each disparate form of intellectual property right. They should also avoid using data exclusivity laws to “design around” the problems found in the patent system.

A decade ago, the pharmaceutical industry and its supportive policymakers and commentators repeatedly used the \$800 million figure to justify stronger protection for pharmaceuticals.<sup>69</sup> Even if one refrains from questioning the accuracy of this heavily criticized figure<sup>70</sup>—a big if—the problem is obvious when the same figure has been used to justify every new form or level of protection for pharmaceuticals. After all, if the patent term has already been extended to provide additional incentives, the need for new data exclusivity laws may have greatly reduced.<sup>71</sup> Once the intellectual property system has provided enough incentives for drug development, any additional protection a country offers will be a windfall. Not only will such protection be unnecessary, but the protection could reduce access to medicines while increasing public health expenditures.

The third recommendation pertains to the need for policymakers and commentators to abandon the binary debate on the protection of clinical trial data. On one end of the spectrum is no protection. On the other end are strong property rights in these data, such as those granted through

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<sup>67</sup> See CORREA, *supra* note 25, at 382; DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 429 (3d ed. 2008); Yu, *Political Economy*, *supra* note 11, at 783.

<sup>68</sup> See Meir Perez Pugatch, *Intellectual Property, Data Exclusivity, Innovation and Market Access*, in *NEGOTIATING HEALTH*, *supra* note 13, at 97, 100; Peter K. Yu, *Intellectual Property and the Information Ecosystem*, 2005 MICH. ST. L. REV. 1, 1.

<sup>69</sup> See INT'L FED'N PHARM. MFRS. & ASS'NS, *A REVIEW OF EXISTING DATA EXCLUSIVITY LEGISLATION IN SELECTED COUNTRIES* 3 (4th rev. ed. 2005).

<sup>70</sup> Commentators have widely questioned this industry-supplied figure. See, e.g., MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 44–45 (rev. ed. 2005).

<sup>71</sup> See Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419 (2012); Yu, *Political Economy*, *supra* note 11, at 784–85.

a data exclusivity regime. In between these two ends are many different options for protecting clinical trial data.

For example, NAFTA focuses on data reliance, the TRIPS Agreement targets the disclosure and unfair commercial use of data,<sup>72</sup> and the TPP Agreement and other TRIPS-plus agreements require the establishment of a market exclusivity regime. In addition, Jerome Reichman explored the use of a cost-sharing or liability-rule approach to compensate for the high costs of clinical trials.<sup>73</sup> He further underscored the need to “rationalize the pharmaceutical supply chain by treating clinical trials as a global public good under a system that apportions costs to all participants and guarantees open access to the resulting data.”<sup>74</sup> Aaron Fellmeth also advanced a readjustable royalties model that allows “for the calculation of royalty payments to the initial registrant by subsequent registrants.”<sup>75</sup>

All of these options are possibilities available to countries eager to consider protection for clinical trial data. Whether one option is preferable to another will largely depend on local needs, interests, conditions, and priorities. The need to choose between these multiple options is indeed why policymakers and commentators have emphasized *ad nauseum* the need for flexibilities in the international intellectual property system.<sup>76</sup>

The fourth recommendation covers the need for empirical support before the introduction of new data exclusivity protection or an increase in such protection. Thus far, policymakers and commentators have noted the need for stronger data exclusivity laws to compensate for the limited protection for biologics under the existing patent system.<sup>77</sup> They have also built a strong and convincing case explaining why the development of orphan drugs needs strong data exclusivity protection.<sup>78</sup> Drawing on the tremendous potential brought about by big data analytics, they may even call for new incentives to induce pharmaceutical developers to upgrade legacy technology and to invest in new analytical tools to optimize innovation, improve clinical trial efficiency, and strengthen drug quality, safety, and efficacy.<sup>79</sup>

For illustrative purposes, consider the proposal calling for stronger data exclusivity protection in the area of biologics. While the Author remains doubtful that countries that are unlikely to develop a strong industry in this area will need such protection, empirical data can easily prove or disprove such a need. Moreover, just because such protection is needed in the area of biologics does not mean that the same protection should be extended to, or increased across, all

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<sup>72</sup> See NAFTA, *supra* note 6, art. 1711.6; TRIPS Agreement, *supra* note 7, art. 39.3.

<sup>73</sup> See Reichman, *supra* note 19, at 144–48.

<sup>74</sup> *Id.* at 134.

<sup>75</sup> Fellmeth, *supra* note 13, at 482–99.

<sup>76</sup> See Yu, *The International Enclosure Movement*, *supra* note 36, at 869–70.

<sup>77</sup> See Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 735–36 (2010).

<sup>78</sup> See Skillington & Solovy, *supra* note 11, at 10.

<sup>79</sup> See 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>; 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/>.

fields of technology. Instead, policymakers and commentators should carefully tailor the new protection to only those areas that have empirically proven needs.

The final recommendation involves efforts to explore whether open-access arrangements can help lower the costs of conducting clinical trials.<sup>80</sup> As the U.N. Secretary-General's High-Level Panel on Access to Medicines noted in its report:

Governments should 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](http://clinicaltrials.gov) or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.<sup>81</sup>

A highly welcoming development in this area is the new publication policy of the European Medicines Agency. Under this policy, the agency proactively publishes clinical trial data that have been submitted to the agency after January 1, 2015, for initial marketing authorization.<sup>82</sup> 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.<sup>83</sup> The publication of these data will be highly useful to researchers and follow-on drug developers.

In addition, because researchers and follow-on developers in one country can easily use the data disclosed in another country, regulatory authorities can further explore collaborations with their counterparts in other countries or regions. While concerns remain about the unconsented sharing of undisclosed proprietary test data among regulatory authorities—leading to new provisions covering “the submission of evidence of a prior marketing approval of the product in another territory”<sup>84</sup>—the open access arrangements championed by the European Medicines Agency may justify greater public, and hopefully global, sharing of clinical trial data. After all, those originators that have submitted data to this agency for marketing approval are well aware of the agency's new publication policy.

## CONCLUSION

Since the TRIPS negotiations in the late 1980s and early 1990s, the protection of clinical trial data has become increasingly contentious. Although data exclusivity protection has still not garnered as much policy and scholarly attention as the three main branches of intellectual property rights—namely, copyright, patent, and trademark—the importance of such protection cannot be overlooked. In recent years, data exclusivity laws have generated considerable debate, thanks to the advent of big data analytics, the fast-paced development of biologics and personalized

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<sup>80</sup> Thanks to Nicholson Price for raising interesting questions in this area.

<sup>81</sup> U.N. SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES, REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES REPORT: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 37 (2016).

<sup>82</sup> See EUROPEAN MEDICINES AGENCY, EUROPEAN MEDICINES AGENCY POLICY ON PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE (2014), [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2014/10/WC500174796.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf).

<sup>83</sup> See *id.*

<sup>84</sup> TPP Agreement, *supra* note 2, art. 18.50.1(b).

medicines, and the proliferation of new standards in TRIPS-plus bilateral, regional, and plurilateral trade agreements. In view of these developments—and their attendant concerns, challenges, and complications—this Article calls on policymakers and commentators to devote greater attention to this increasingly important and contentious area.