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Cover Page Footnote

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Protection of Test Data Under Article 39.3 of the TRIPS Agreement: Advancements and Challenges After 25+ Years of Interpretation and Application

Eric M. Solovy*

Abstract:

Among the types of intellectual property rights covered by the TRIPS Agreement, WTO Members must, pursuant to Article 39.3, protect certain test and other data submitted "as a condition of approving the marketing of pharmaceutical or of agricultural chemical products." Such protection provides the incentives necessary for the biopharmaceutical industry to conduct the lengthy, expensive multi-phased clinical testing that is required to demonstrate the safety and effectiveness of a new drug or vaccine.

Test data protection has become increasingly more important to the development of new medicines in the past several years. That is in significant part because biologics (i.e., large chemical molecules such as proteins, made by biotechnology) have revolutionized medicine with more effective treatments for cancer, rheumatoid arthritis, asthma, and other diseases. To deliver on their full potential for patients, biologics need a sufficient period of test data protection.

This article first sets out the proper interpretation of Article 39.3 of the TRIPS Agreement, highlighting the critical flaws in the interpretations set out by several academics and international organizations over the past several years. Then, the sections that follow consider specific examples of how the obligations in Article 39.3 have been interpreted and, in fact, implemented over the past quarter-century, and evaluate the consistency of such interpretation and implementation with the proper interpretation of that provision.

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In particular, Section III looks to countries that have clarified and, in some instances, expanded the coverage and scope of Article 39.3, including through Free Trade Agreements ("FTAs"), some of which include so-called "TRIPS-plus" provisions. Section IV then considers countries that have reportedly failed to faithfully implement the requirements of Article 39.3, whether through a deficiency in their laws and regulations, or through a failure to enforce or implement laws and regulations that otherwise would appear on their face to satisfy Article 39.3. Section V provides concluding remarks about the state of global protection of test data, and the way forward.

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I. INTRODUCTION

More than twenty-five years have now passed since the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), an agreement that is often considered to be the most controversial of the World Trade Organization ("WTO") agreements.[1] Pursuant to the TRIPS Agreement, WTO Members must protect multiple forms of intellectual property rights, including, *inter alia*, patents, trademarks, copyrights, and – the topic of this article – "undisclosed information." The protections that must be accorded are not just the substantive rights found in Part II of the TRIPS Agreement, but also effective *enforcement* of those rights pursuant to Part III, as confirmed most recently in the WTO dispute against Saudi Arabia's failure to allow for civil or criminal enforcement of its copyright law.[2]

While patents are one form of intellectual property on which R&D-intensive industries heavily rely, protection of undisclosed data under Article 39 of the TRIPS Agreement provides another critically important form of protection, particularly for innovative biopharmaceutical companies. These two forms of intellectual property protection operate in parallel, and separately. For example, protection of undisclosed information (including test data) is available in respect of a pharmaceutical product, irrespective of whether the same product also enjoys patent protection. It is important to note that, even with one or both types of protection, pharmaceutical products may nevertheless still need to compete with one or more products that can be used to treat (or protect against, in the case of a vaccine) the same disorder or disease, to the extent those additional products do not infringe a valid patent or rely on the same test data during the term of its protection. To be clear, Article 39 of the TRIPS Agreement does nothing to prevent a competitor from independently generating and submitting their own test data for a competing pharmaceutical product.

Among the types of undisclosed information covered by the TRIPS Agreement, WTO Members must, pursuant to Article 39.3, protect certain test and other data submitted "as a condition of approving the marketing of pharmaceutical or of agricultural chemical products."[3] Such protection provides the incentives necessary for the biopharmaceutical industry to conduct the lengthy, expensive multi-phased clinical testing that is required to demonstrate the safety and effectiveness of a new drug or vaccine. Regulators around the world generally require that such testing also

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[1] Agreement Establishing the World Trade Organization, § 7 art. 39, Annex IC, 1994, 33 I.L.M. 1197-1225 [hereinafter TRIPS Agreement].

[2] Panel Report, *Saudi Arabia – Protection of Intellectual Property Rights*, WT/DS567/R (circulated June 16, 2020), para. 8.1(b) (concluding that Qatar established that Saudi Arabia "acted in a manner inconsistent with Article 42 and 41.1 of the TRIPS Agreement" with respect to civil enforcement procedures, and "acted inconsistently with Article 61 of the TRIPS Agreement," with respect to criminal procedures and penalties).

[3] TRIPS Agreement, *supra* note 1, at art. 39.3.

demonstrate that the process used to manufacture the product reproduces the tested product safely and consistently and that the manufacturing facilities meet basic safety requirements. Importantly, only a fraction of tested products actually obtain final approval, such that the actual cost of developing the data from both successful and unsuccessful products must be recouped from sales of those medicines and vaccines that are actually approved.

Recent studies estimate that it takes, on average, USD 2.6 billion to develop and win approval for a new drug.[4] A significant portion of this funding goes towards developing the data necessary for regulatory approval. It has been estimated that more than 60% of the total cost of bringing a new medicine to market arises from clinical trials, including trials for drugs that are ultimately not approved.[5] Indeed, a 2014 study by the Tufts Center for the Study of Drug Development found that less than 12% of new drugs successfully made it through clinical trials to approval.[6]

As traditionally understood by those countries that advocated for the inclusion of Article 39.3 in the TRIPS Agreement, including the United States and the European Union,[7] the intellectual property associated with the data submitted to a government for regulatory approval of a pharmaceutical product requires a WTO Member, for a limited period of time, to prevent others (including producers of generic drugs and biosimilars) from relying on that data to demonstrate the safety and efficacy of their own competing product. Such intellectual property protection essentially treats the data developed to demonstrate the safety and efficacy of the drug or vaccine as exclusive to the party that developed it, for a limited period of time.

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[4] *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion*, Tufts Center for the Study of Drug Development (November 18, 2014), https://khn.org/wp-content/uploads/sites/2/2019/02/30e17-pr-coststudy.pdf; Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry*, 47 J. HEALTH. ECON 20, 26 (2016).

[5] PhRMA Special 301 Submission 2022 to the U.S. Trade Representative ("PhRMA's 2022 Special 301 Submission"), at 13, https://www.regulations.gov/comment/USTR-2021-0021-0024 (citing Research!America, *U.S. Investments in Medical and Health Research and Development 2013-2018* (2019), https://www.researchamerica.org/sites/default/files/Publications/InvestmentReport2019_Fnl.pdf).

[6] Joseph A. DiMasi et al., *Briefing: Cost of Developing a New Drug*, Tufts Center for the Study of Drug Development (November 18, 2014), https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf.

[7] *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, 10–17 (2003). The U.S. Orphan Drug Act (1983) provided seven years of marketing exclusivity for those companies that provided test data necessary to get approval for an orphan drug, followed by the Hatch-Waxman Act (1984), which provided five years of protection for test data. The European Union followed suit in 1987, providing 6 to 10 years of test data protection. *See id.* at 10–13.

Thus, in practice, a generic manufacturer wishing to market and distribute a generic pharmaceutical product must either (i) conduct its own clinical trials and submit data from those trials to the national authority, (ii) wait for the expiration of the intellectual property right over the test data of the innovator, or (iii) negotiate a license with the innovator for the use of its test data.

Allowing third parties to rely on the data generated by the originator in order to receive approval of their own pharmaceutical product, at a time before the originator would have been expected to recoup their investment, would provide the competitors with an unfair commercial advantage. Such a windfall would allow a competitor to avoid the high costs of generating the test data and, as a result, enable the competitor to undercut the originator's prices.

Further, without adequate protection, the high cost of developing test data (and the risk of its non-recuperation due to free-riders) may prevent market entry of certain innovative products in the first place. In particular, without data exclusivity, manufacturers often cannot justify the costs of researching and testing certain non-patentable pharmaceutical inventions.

In emerging markets, for example, test data protection can provide the additional incentives needed to develop medicines tailored for the particular needs of those countries. Further, it may also incentivize additional research and local investment on the ground in countries where test data is protected, given the greater certainty that the data generated will be properly protected against competitors. Thus, when commentators such as Yu argue that stronger test data protection "could be highly detrimental" to developing countries by, e.g., "reduc[ing] access to medicines," they apparently fail to consider the way in which the incentives created by such protection may actually benefit such countries, both in the short term and long term.[8]

During the early years of the WTO, back in 2003, G. Lee Skillington and I co-authored an article entitled *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, which aimed to understand Article 39.3 through looking "to the ordinary meaning of the provision in proper context in the same manner as would a WTO dispute settlement panel or the WTO Appellate Body."[9] In that article, interpreting the provision in line with the rules of treaty interpretation in the Vienna Convention on the Law of Treaties ("Vienna Convention" or "VCLT"),[10] we concluded that

> Article 39.3 provides protection against the unjust or unfair application or conversion of certain test and other data to make a

[8] Peter K. Yu, *TRIPS in the Field of Test Data Protection* 5 (Tex. A&M Univ. Sch. of L. Legal Stud. Rsch. Paper No. 20-28 2020), https://ssrn.com/abstract=3716105.

[9] Skillington & Solovy, *supra* note 7, at 5.

[10] Vienna Convention on the Law of Treaties ("VCLT"), 1155 U.N.T.S. 331 (May 23, 1969).

> profit or to obtain a benefit. Such protection must be provided long enough to allow the originator to at least recoup its investment in data production.[11]

Since the publication of that article in 2003, test data protection has become increasingly more important to the development of new medicines. That is in significant part because, in recent years, biologics (i.e., large chemical molecules such as proteins, made by biotechnology) have revolutionized medicine with more effective treatments for cancer, rheumatoid arthritis, asthma, and other diseases.[12] Biologics have also led to new therapies for rare diseases that originally had few or no treatment options. To deliver on their full potential for patients, biologics need a sufficient period of test data protection.

Over the past several years, there have been a number of articles and other publications (including by the United Nations Conference on Trade and Development) that have further opined on the meaning of Article 39.3 of the TRIPS Agreement. And, over this time, WTO Members have, in practice, opted to implement the test data protection requirements of the TRIPS Agreement in a variety of ways.

In this article, I first recall, in Section II, the proper interpretation of Article 39.3 of the TRIPS Agreement, highlighting the critical flaws in the interpretations set out by several academics and international organizations over the past several years. Then, in the sections that follow, I consider specific examples of how the obligations in Article 39.3 have been interpreted and, in fact, implemented over the past quarter-century, and evaluate the consistency of such interpretation and implementation with the proper interpretation of that provision.

In particular, Section III looks to countries that have clarified and, in some instances, expanded the coverage and scope of Article 39.3, including through Free Trade Agreements ("FTAs"), some of which include so-called "TRIPS-plus" provisions. Section IV then considers countries that have reportedly failed to faithfully implement the requirements of Article 39.3, whether through a deficiency in their laws and regulations or through a failure to enforce or implement laws and regulations that otherwise would appear on their face to satisfy Article 39.3. Section V provides concluding remarks about the state of global protection of test data and the way forward.

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[11] Skillington & Solovy, *supra* note 7, at 5.

[12] *See, e.g.*, How Biologics Have Changed the Rules for Pharma, Chemistry World (May 7, 2019), https://www.chemistryworld.com/molecule-to-market/how-biologics-have-changed-the-rules-for-pharma/3010301.article; Biological Medicines Target Disease Solutions, Sanofi, https://www.sanofi.com/en/about-us/biologic-medicines-target-disease-solutions (last visited Jan. 4, 2021).

II. INTERPRETATION OF ARTICLE 39.3 OF THE TRIPS AGREEMENT

Before turning to the varied interpretations and implementation of Article 39.3 of the TRIPS Agreement during the past several years, one must start at the beginning, with the text of the provision subject to interpretation and application. Article 39.3 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.

Thus, Article 39.3. imposes an obligation on Members to take affirmative steps to protect "undisclosed test or other data" from both "unfair commercial use" and "disclosure," subject to the satisfaction of several conditions.

Article 39 is the sole provision in Part II, Section 7 of the TRIPS Agreement, which is entitled "Protection of Undisclosed Information." In addition to requiring protection of test data, it also requires substantive protections against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), as well as protection of trade secrets.

A. Principles of Treaty Interpretation

Proper interpretation of the TRIPS Agreement must begin with the text itself. WTO adjudicators are mandated to apply the customary rules of treaty interpretation.[13] The WTO Appellate Body and dispute settlement panels have consistently found that Articles 31 and 32 of the VCLT codify such customary rules, which they must apply.[14] Article 31.1 of the VCLT provides that a treaty shall be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose."[15] In determining "ordinary

[13] Marrakesh Agreement Establishing the World Trade Organization, art. 3.2, Annex 2, Apr. 15 1994, 1869 U.N.T.S. 401 [hereinafter WTO Agreement].

[14] Appellate Body Report, *China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, WT/DS363/AB/R, adopted 19 January 2010, DSR 2010:I, ¶ 348; Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/AB/R, adopted 20 April 2005, DSR 2005:XII, ¶ 164 (and Corr.1, DSR 2006:XII, p. 5475); Appellate Body Report, *United States – Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada*, WT/DS257/AB/R, adopted 17 February 2004, DSR 2004:II, ¶ 58.

[15] VCLT, *supra* note 10, art. 31.1.

meaning," WTO panels and the Appellate Body have often relied extensively and expressly on dictionary definitions.[16] If the rules of interpretation in Article 31 of the VCLT yield a vague or absurd result, supplementary means of interpretation (including negotiating history) may be invoked. Articles 31 and 32 of the VCLT are intended to direct an interpreter to "focus on ascertaining the *common* intentions of the parties."[17]

While some have argued that ambiguities in the language of the TRIPS Agreement permit virtually limitless flexibility in how Members may interpret the provisions, as explained by Solovy and Krishnamurthy when commenting on the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines ("HLP Report"):

> there is no basis—either in public international law or in WTO practice—for the proposition advanced in the HLP Report, i.e., that WTO Member governments are "free" to interpret terms in the WTO agreements as they see fit in the absence of a specific definition of that term in the treaty. The fact that granting such "freedom" might make it easier for a Member, for example, to provide short-term access to a medicine does not somehow change the fundamentals of treaty interpretation.
>
> The absence of an explicit definition in a treaty, including for a term of art, may not be taken as an invitation by an individual WTO Member to interpret the treaty as if it were solely an instrument of national law. Rather, the term in question must be interpreted using the ordinary meaning of those terms, interpreted in their context, and in view of the object and purpose of the TRIPS Agreement. This is irrespective of Article 1 of the TRIPS Agreement, which provides, in relevant part: "Members shall give effect to the provisions of this Agreement." While Members are free to determine the method of domestic treaty execution (i.e., the how), they are not free to determine the matter to be incorporated into their own legal system (i.e., the what).[18]

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[16] *See*, *e.g.*, Appellate Body Reports, *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Second Recourse to Article 21.5 of the DSU by Ecuador*, WT/DS27/AB/RW2/ECU, adopted 11 December 2008; Corr.1 / *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 of the DSU by the United States*, WT/DS27/AB/RW/USA and Corr.1, adopted 22 December 2008, DSR 2008:XVIII, p. 7165*;* Appellate Body Report, *China — Publications and Audiovisual Products*, *supra* note 14, at ¶ 348.

[17] Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WT/DS269/AB/R, WT/DS286/AB/R, adopted 27 September 2005, and Corr.1, DSR 2005:XIX, p. 9157.

[18] Eric M. Solovy & Pavan S. Krishnamurthy, *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary General's High-Level Panel Report on Access to Medicines*, 50 GEO. WASH. INT'L L. REV.

With this understanding in mind, the next subsections briefly review the conditions of protection under Article 39.3 of the TRIPS Agreement and the scope of that protection.

B. Conditions for Protection under TRIPS Article 39.3

Based on the ordinary meaning of Article 39.3, WTO Members are obligated to protect test data that meets five criteria, namely:

(1) The Member must require that the data is submitted as a condition for obtaining marketing approval for a product in that Member;
(2) The product for which marketing approval is sought is a pharmaceutical or agricultural chemical product;
(3) The product for which marketing approval is sought utilizes a new chemical entity;
(4) The data is undisclosed at the time of submission; and
(5) The generation of the data required considerable effort.[19]

If each of these criteria is met, then the data must be protected in accordance with the requirements of Article 39.3.

First, the data subject to protection is that which a Member requires to be submitted "as a condition of approving the marketing of" the product.[20] Thus, the submission of data must be *necessary* to obtain approval and not provided on a voluntary basis.[21] However, the protection required under Article 39.3 is not limited to data that is submitted directly to the regulatory agency of the Member that requires the data. It could, for example, extend to data submitted to an independent research facility for analysis.[22] Or the data could instead be submitted to the regulator of another country, with a WTO Member relying on approval by that other country (and, therefore, indirectly on the data itself) for its own consideration and approval. Thus:

> In such cases, Members are, in fact, requiring submission of otherwise protectable data for approval, albeit indirectly. In other words, but for the submission of test data to another country, these Members would not approve sale of the product in their territories. The countries in the group upon which certain Members rely for reviewing test data are essentially agents of the Members—agents to which the countries require submission of test data. Therefore, it follows that those Members must protect the data, even though the

69, 89 (2017).

[19] Skillington & Solovy, *supra* note 7, at 23.

[20] WTO Agreement, *supra* note 13; TRIPS Agreement, *supra* note 1.

[21] *See* Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46 FLA. ST. U. L. REV. 641, 650—651 (2019) (hereinafter "Yu, *Data Exclusivities*"); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF ANTITRUST AND UNDISCLOSED INFORMATION 286 (2008).

[22] Skillington & Solovy, *supra* note 7, at 24; CARVALHO, *supra* note 21, at 286.

data were submitted to a different country.[23]

Yu, also citing Correa, contends that when a regulator in one country relies on regulatory approval in a second country in granting its own approval, it is *not* a reliance on data submitted "as a condition of approving the marketing of regulated products" and Article 39.3 would simply not apply.[24] This is incorrect. Article 39.3 refers to a requirement of "submission of undisclosed test or other data," and does not specify that such submission is made to the Member whom receives the generic producer's application.[25] Yu and Correa therefore read a limitation into Article 39.3 that is neither explicit nor otherwise implicit.

Second, the product for which marketing approval was sought must be a "pharmaceutical or agricultural chemical product."[26] The TRIPS Agreement does not contain a definition of that phrase, which has not served to be controversial. With respect to "pharmaceutical" product, the ordinary meaning is a product "used in pharmacy, of the nature of a medicinal drug."[27]

Third, the products involved must "utilize new chemical entities."[28] The TRIPS Agreement does not provide a definition for "new" or "chemical entity." Here, the explicit purpose of Article 39.3 is to protect against acts of unfair commercial use of test and other data arising from the Member's regulatory approval process. Understanding that context (and the object and purpose), the term "new" must refer to a chemical entity's status in the Member's domestic regulatory system, rather than something that has not previously been known to exist anywhere in the world. [29] As set out in Skillington and Solovy, it would violate "this purpose and def[y] logic to encourage introduction only of recently invented products, and to discourage simultaneously the entry of safe and effective products derived from naturally occurring substances, or of substances that were known to the public but not previously marketed as pharmaceutical or agricultural

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[23] Skillington & Solovy, *supra* note 7, at 25. *See also* CARVALHO, *supra* note 21, at 287 ("If a country grants marketing approval to one product based on a registration previously issued in another country, the sanitary controls of which it deems accurate and reliable, one should not forget that such a registration was obtained by means of the submission of the data. Therefore, indirectly, the registration in the second country would rely on the data submitted by the originator in the first country. Or, in other words, the second country would still, even if in an indirect manner, require the submission of undisclosed test or other data.").

[24] Yu, *supra* note 21, at 658 (citing Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights A Commentary on the TRIPS Agreement 377 (2007)).

[25] Skillington & Solovy, *supra* note 7, at 26.

[26] *Id.*

[27] *Pharmaceutical*, OXFORD ENGLISH DICTIONARY (3d ed. 2005).

[28] TRIPS Agreement, *supra* note 1, at art. 39.3.

[29] Skillington & Solovy, *supra* note 7, at 26.

chemical products."[30]

Some commentators have interpreted the term "new" as having been intentionally left undefined in TRIPS Agreement negotiations so that Members would have the discretion to redefine the term in domestic legislation.[31] Correa, in particular, suggests that the ambiguity in the dictionary definition of "new" allows Members considerable discretion in defining the concept, while admitting that "presumably does not impose a patent-like standard of novelty."[32] As such, Correa believes Members may limit their protection to products that meet a patent-like novelty standard, or are new to the world - not just the country where the regulatory approval is sought.[33] While Yu takes the position that Article 39.3 does not "require the relevant entities to meet the novelty standard commonly found in patent law," he contends that it is an ambiguous term that permits Members to "wide discretion to set their own standards."[34] Ragavan similarly argues that the term "new" provides "adequate flexibility to construe the term differently" such that there is "nothing to prevent a member from treating a chemical whose patent has been invalidated or denied as not being 'new'."[35]

Yet, as with every other term in the TRIPS Agreement, "new" does have a meaning that can be determined through the VCLT rules of interpretation. It is the treaty text, interpreted in accordance with these rules of interpretation, that can, contrary to Ragavan's assertion, "prevent a member from treating a chemical whose patent has been invalidated or denied as not being 'new'."[36] If a WTO Member were to adopt and apply an overly narrow patent-like interpretation of "new," this would ignore the context and object and purpose of the provision and fail to protect all of the test data that must be protected pursuant to Article 39.3. This provision appears in the context of a section (i.e., Part II, Section 5) focusing on the protection of information that has not been publicly disclosed, not (as in the case of Part II, Section 7) in a section concerned with protecting and incentivizing inventions (and public disclosure of such inventions). Here, the object and purpose of Article 39.3 is elimination of acts of unfair commercial use of test and other data arising from a Member's regulatory

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[30] *Id.* at 18.

[31] *See*, *e.g.*, Yu, *supra* note 21, at 650.

[32] Carlos María Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHICAGO J. INT'L L. 69, 74-75 (2002).

[33] *Id.*

[34] Yu, *Data Exclusivities*, *supra* note 21 at 663. *See also* Yu, *supra* note 8, at 10 (stating that Article 39.3 "does not require the relevant entities to meet the novelty standard commonly found in patent law").

[35] Srividhya Ragavan, *The (Re)Newed Barrier to Access to Medication: Data Exclusivity*, 51 AKRON L. REV. 1163, 1182 (2017).

[36] *Id.*

approval process. Any interpretation of Article 39.3 should also account for the overall object and purpose of the TRIPS Agreement as set out in Article 7, which envisions "a balance of rights and obligations" accounting for the interests of creators (i.e., here, originators of the test data) and the ultimate beneficiaries (i.e., recipients of the medicines and vaccines) of the undisclosed information.

Turning to the term "chemical entities," which refers to something "utilize[d]" by a "pharmaceutical" or "agricultural chemical product," the ordinary meaning of "chemical" (when used as an adjective, such as in this phrase) is "[m]ade from or consisting of chemicals; of the nature of a chemical."[37] The ordinary meaning of "entity" is "[s]omething that has a real existence."[38] Thus, a "chemical entity" is simply something that is made from or consisting of chemicals. As all matter is made up of chemicals, this is a particularly broad concept.[39]

Nevertheless, some commentators have argued that biologics (i.e., large chemical molecules such as proteins, made by biotechnology) are not "chemical entities" within the meaning of Article 39.3 because they "involve biological materials."[40] Ragavan, for example, appears to argue that Article 39.3 does not cover biological materials of any kind simply because the text refers to "chemical entities" rather than biological materials.[41] Yet, Ragavan fails to even consider the ordinary meaning of "chemical entities;" if she had done so (as required by the VCLT rules of treaty interpretation), she would have determined that there is nothing in the term "chemical entities" that would allow exclusion of biological materials, which are also made up of chemicals. As Carvalho correctly explains, "the notion of chemical entities covers biotechnology products, including genes and genetically modified genes, *for they constitute chemical organic molecules*."[42] Further, the context of Article 39.3 demonstrates an intent to protect data submitted in order to receive regulatory approval for marketing of "pharmaceutical" products (as well as agricultural chemical products), and biologics are understood to be a type of "pharmaceutical" product.

Fourth, the data must have required "considerable effort" to develop. Although undefined, the ordinary meaning of "considerable effort" is "the concentrated or special activities, physical or mental, that are extensive in scope or duration."[43] The conduct of clinical trials necessary for regulatory marketing approval, which require years of research and many millions of

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[37] *Chemical*, OXFORD ENGLISH DICTIONARY (3d ed. 2008).

[38] *Entity*, OXFORD ENGLISH DICTIONARY (2d ed. 1989).

[39] *See, e.g.*, Chemistry is Everywhere, American Chemical Society, https://www.acs.org/content/acs/en/education/whatischemistry/everywhere.html (last visited Oct. 28, 2020) ("chemists believe that everything is made of chemicals.").

[40] *See* Yu, *Data Exclusivities*, *supra* note 21, at 690.

[41] Ragavan, *supra* note 35, at 1181.

[42] CARVALHO, *supra* note 21, at 287 (emphasis added).

[43] Skillington & Solovy, *supra* note 7, at 28.

dollars in investment, would easily fall within the scope of this provision.

Fifth, the "test or other data" must be "undisclosed" to the public at the time of submission to a regulatory agency. Thus, information that is already in the public domain, such as data published in scientific journals, is not guaranteed protection under Article 39.3.

C. Nature of Protection under Article 39.3 of the TRIPS Agreement

Having briefly recalled the conditions that must be satisfied before a Member is obligated to protect test data, the next question becomes *how* such data must be protected. As set out below, Article 39.3 requires two types of protection: (1) protection of the data against "unfair commercial use"; and (2) protection of the data against "disclosure," subject to two exceptions.

1. Protection Against Unfair Commercial Use

The primary obligation of WTO Members under Article 39.3 is to protect data submitted for regulatory approval against "unfair commercial use." The practical parameters of this term are not defined in the TRIPS Agreement, such that the principles of treaty interpretation must be applied to understand the metes and bounds of the requirement.

The ordinary meaning of "unfair" is "not equitable, unjust; not according to the rules, partial."[44] "Commercial" means "engaged in commerce; of, pertaining to, or bearing on commerce" or "interested in financial return rather than artistry; likely to make a profit; regarded as a mere matter of business."[45] In the specific context of Article 39.3, Carvalho explains that commercial use means "to use the data for the single commercial purpose they can have, which is to support an application for marketing approval."[46] Finally, "use" means an "action of using or state of being used; application or conversion to some purpose" and "ability to be used, especially for a particular purpose; usefulness; advantage."[47] Thus, the phrase "unfair commercial use" of test data refers to the unjust application or conversion of the data in a manner that yields a profit or other business benefit.

Relevant for the current context, if a WTO Member, at the request of a competitor of the originator of data, relied on data submitted by the originator in a manner that benefits the competitor, this would constitute an application or conversion of the data that helps the competitor to make a profit, *i.e.*, "commercial use." Where such reliance occurs before a period of time adequate for the originator to have at least recouped the costs

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[44] *Unfair*, OXFORD ENGLISH DICTIONARY (2d ed. 1989).

[45] *Commercial*, OXFORD ENGLISH DICTIONARY (2d ed. 1989).

[46] CARVALHO, *supra* note 21, at 271.

[47] *Use*, OXFORD ENGLISH DICTIONARY (3d ed. 2011).

involved in the generation of the data, this use would be unfair, *i.e.*, "unfair commercial use." The unfairness of such commercial use would stem from the fact that an originator invested effort and resources in creating the data, at the direction of the government, after which a government would allow a competitor to freeride on that data.

Along the same lines, in a paper submitted to the WTO's TRIPS Council in 2001, the European Union explained that, where a Member has a marketing approval procedure, and that procedure requires the submission of undisclosed test or other data, Article 39.3 provides an obligation to protect such data from unfair commercial use.[48] The European Union went on to state that "the most effective method of doing so is to deny the regulatory authorities the possibility of relying on such data for a reasonable period of time," for the purposes of granting marketing approval of a competing product.[49] In 2000, the European Union prepared a paper that referenced the interpretations of "unfair commercial use" set out by the United States and New Zealand in 1995, and concluded that such statements suggest that "the 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."[50]

The question of fairness (in this case "unfair[ness]") arising here is similar to that which underpins the entire system of intellectual property protection covered by the TRIPS Agreement – the notion that the effort and investment in the creation of intellectual property must be properly incentivized, and that such intellectual property must be protected from competitors who may seek a windfall from the investments and efforts that

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[48] Communication from the European Communities and their member states, IP/C/W/280 June 12, 2001 (01-2903), https://www.wto.org/english/tratop_e/trips_e/paper_eu_w280_e.htm.

[49] *Id. See also* European Commission, Questions on TRIPs and Data Exclusivity, an EU Contribution 21 (2001), https://www.concurrences.com/IMG/pdf/eu_-_compulsory_licensing.pdf, as referenced by Yu, *supra* note 8 ("On its face, Article 39.3 of TRIPs contains an obligation to protect test data against 'unfair commercial use', and it seems that the most effective way to fulfil that objective, as envisaged by the TRIPs negotiators, is to provide for data exclusivity over a reasonable period of time. Whether any system other than data exclusivity over a reasonable period of time would meet the requirements of Article 39.3 of the TRIPS Agreement is to be assessed on a case-by-case basis, but examples of actual application by WTO Members of alternative -and TRIPs compliant- systems to nonreliance over a reasonable period do not appear to exist.").

[50] European Commission, Questions on TRIPs and Data Exclusivity, an EU Contribution 19 (2001), https://www.concurrences.com/IMG/pdf/eu_-_compulsory_licensing.pdf (citing Office of the General Counsel, U.S. Trade Representative, *The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3*, unattributed paper for submission in bilateral discussions with Australia (May 1995) and Government of New Zealand, *Protection of Undisclosed Information and Control of Anti-Competitive Practices* (APEC TRIPs Seminar 1995)).

led to the creation of that intellectual property. However, a key difference is that, in the context of Article 39.3, the commitment of effort and resources for the creation of the protected intellectual property (*i.e.*, data) occurs pursuant to a specific requirement imposed by the government (*i.e.*, as a condition for marketing approval). As such, the unfairness if a government were to permit competitors of the originator to free ride on the effort and resources is even more pronounced in the context of data protected under Article 39.3.

At the same time, after a certain period of time (commonly, five years or more), WTO Members generally accept that reliance will not result in unfairness, such that the market will be more open to competition. After that time, regulators allow for reliance on an originator's data for a generic drug that has the identical active ingredient, and exhibits the same behavior in a patient, as the product subject to the data protection. As biosimilars (i.e., biologics that are similar to a previously approved biologic) are not "identical" to the original product, in addition to reliance on the prior data and approval, additional clinical data is generally required to support approval.

In opposing the interpretation set out above, some commenters have argued that "unfairness" is an inherently subjective standard, meaning that implementation of Article 39.3 should be left *fully within the discretion of WTO Members*. For example, Correa has posited that the "concept of unfairness is relative to the values of a particular society at a given point in time" and, as such, there is no universal standard by which to judge whether a standard is unfair.[51] Given his view that exclusive rights entail heavy costs and ethical concerns, Correa argues the ambiguity should be interpreted as granting Members extreme flexibility to implement Article 39.3 to accommodate their own cultural values and policy needs.[52] Yu appears to agree, arguing that data exclusivity "is a TRIPS-plus demand that has gone beyond the WTO requirements," and he does not find that any exclusivity requirement can be derived from the "unfair commercial use" obligation.[53] Ragavan similarly argues – without any attempt to apply the VCLT rules of treaty interpretation – that because "unfair commercial use" is undefined in the TRIPS Agreement, developing country WTO Members are accorded flexibility which they should use "to define the terms strictly to include uses of the data by a commercial/corporate entity but in a manner leaving out the use of the data by government authorities."[54]

This overly nebulous interpretation is deeply flawed, as it would effectively render the first sentence of Article 39.3 meaningless.[55] Members

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[51] Correa, *supra* note 32, at 77.

[52] *Id.* at 82.

[53] Yu, *Data Exclusivities*, *supra* note 21, at 658.

[54] Ragavan, *supra* note 35, at 1178.

[55] *See, e.g.*, Appellate Body Report, *United States – Standards for Reformulated and*

would have had the same freedom Correa describes to legislate test data protection as they see fit even if they had not bound themselves by the terms of Article 39.3. Of course, a proper interpretation of treaty provisions under the Vienna Convention does not permit every Member to decide for itself what each provision means; provisions can and must be interpreted, and there are rules and principles for doing so.[56]

In a "technical brief" on test data protection issued under the name of WHO's Regional Office to Southeast Asia, the authors argue that Article 39.3 does not require WTO Members to provide any protection against reliance by generic competitors because "the text of the Article does not make any reference whatsoever to exclusivity or exclusive rights."[57] Yet, where the originator of the data turns over its valuable data to a government regulator as a condition of receiving regulatory approval, the resulting intellectual property right is qualitatively different than the "exclusive right" of an individual right holder such as, e.g., a patent right (under Article 28.1 of the TRIPS Agreement) or a trademark right (under Article 16.1). That is because, after the data has been voluntarily shared with a government, the initial burden to protect that data then falls directly on WTO Members (and their respective regulators) rather than on the right holder.

It should also be noted that Article 39.2, which requires that WTO Members accord trade secret protection, likewise does not use the term "exclusive right;" this, of course, does not mean that a right holder can be forced to share the trade secret (or the benefits thereof) with another entity without consent.

The WHO's brief then goes on to propose an unduly narrow interpretation of the word "use" in the phrase "unfair commercial use." In particular, it argues that "the generic manufacturer never uses the originator's data, and does not even have access to them" and that regulatory authorities also "do not normally use the originator's data."[58] As noted above, "use" means an "action of using or state of being used; application or conversion to some purpose" and "ability to be used, especially for a particular purpose; usefulness; advantage."[59] This definition is broad enough to cover not only direct use, but also indirect use. Here both the generic competitor and a government regulator would use the originator's data if a generic drug is approved based on its identity or similarity with the originator drug. Without use (i.e., reliance on) such data, the government regulator would have no basis on which to approve the

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Conventional Gasoline, WT/DS2/AB/R, adopted 20 May 1996, DSR 1996:I, p. 3.

[56] Solovy & Krishnamurthy, *supra* note 18, at 81-82.

[57] *Data Exclusivity and Other "TRIPS-Plus" Measures*, WHO Regional Office for South-East-Asia (2017), https://apps.who.int/iris/handle/10665/272979.

[58] *Id.*

[59] *Supra* note 47.

drug.

Additionally, the WHO technical brief provides that, because a regulatory agency "is not a commercial organization," any use would not be considered "commercial use."[60] This ignores the fact that the generic company, which would attempt to rely on the valuable data produced by the originator and submitted to the government (and thereby would indirectly "use" the data), is a commercial enterprise that benefits from sale of medicines. As explained by Scafidi, because a "later application submitted without independent test data could not meet government standards without the existence of the original test data," the third-party applicant "thus derives commercial advantage from a regulatory process that makes use of undisclosed test data."[61]

Others have argued that the negotiating history of Article 39.3 of the TRIPS Agreement supports an interpretation that does not require Members to prevent generic producers from relying upon the data submitted by an originator for any set period of time. For example, Yu argues that "the removal of the Brussels draft language [which included a specific reference to reliance] strongly supports the view that the TRIPS Agreement does not prohibit regulatory authorities from relying on previously submitted test or other data."[62] By contrast, also recalling the removal of the same language, the European Union has argued that "both the logic and the negotiation history of Article 39.3 of the TRIPS Agreement leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair use as prescribed by Article 39.3."[63]

That said, according to Article 32 of the VCLT, recourse to the negotiating history is secondary to the interpretation that derives from the ordinary meaning, considered in view of the context and object and purpose.[64] There is no ambiguity in the wording of Article 39.3 that undisclosed test data is to be protected against unfair commercial use. The fact that no set duration of protection has been prescribed does not render the requirement of protection, or the scope of such protection, ambiguous.

In any event, barring a clear understanding of why the language cited

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[60] *Data Exclusivity and Other "TRIPS-Plus" Measures*, *supra* note 57.

[61] Susan Scafidi, *The "Good Old Days" of TRIPS: The U.S. Trade Agenda and the Extension of Pharmaceutical Test Data Protection*, 4 YALE J. HEALTH POL'Y L. & ETHICS 341, 346 (2004).

[62] Yu, *Data Exclusivities*, *supra* note 21, at 656.

[63] European Commission, Questions on TRIPs and Data Exclusivity, an EU Contribution 20 (2001), https://www.concurrences.com/IMG/pdf/eu_-_compulsory_licensing.pdf.

[64] Article 32 of the VCLT provides: "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) [l]eaves the meaning ambiguous or obscure; or (b) [l]eads to a result which is manifestly absurd or unreasonable."

by Yu was removed during negotiations, it is of little assistance. It may be that the negotiators had come to the understanding that reliance was prohibited even without the specific reference, or that they simply could not agree on the precise minimum time period that was deemed appropriate. Indeed, as noted in Skillington and Solovy, this is precisely what one commentator, Jacques Gorlin, explained back in 1999:

> 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.[65]

This understanding of the negotiating history was also supported by Carvalho, who (after performing a lengthy, detailed review of the negotiating history) explained as follows:

> [A]lthough draft language that would clarify the meaning of the term 'unfair commercial use' has not been retained, the text of Article 39.3 contains elements that lead to the inevitable conclusion that the primary purpose of that provision is not to protect test data from disclosure but rather from preventing governments from relying directly or indirectly on data provided by the first registrant and thus saving its competitors the efforts of developing and submitting their own test data . . . .[66]

The United Nations Conference on Trade and Development ("UNCTAD") published a "Reference Guide," entitled *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries* (hereinafter "UNCTAD Guide"), that takes the erroneous position that "the TRIPS Agreement in Article 39 does not contain language that would prohibit the reliance on the original test data."[67] While the Reference Guide

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[65] Skillington & Solovy, *supra* note 7, at 20 (quoting Jacques J. Gorlin, An Analysis of the Pharmaceutical-Related Provisions of the TRIPS (Intellectual Property) Agreement 48 (1999)).

[66] CARVALHO, *supra* note 21, at 258-59. Carvalho goes on to state that this protection against reliance would be provided "unless those competitors obtain authorization from the first registrant or, if the law so permits, pay him compensation." *Id.*

[67] United Nations Conference on Trade and Development, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide*, at 163, UNCTAD/DIAE/PCB/2009/19 (adopted Apr. 29, 2011) ("UNCTAD Reference Guide"). Similarly, an April 2020 "Policy Brief" by the South Centre NGO opines that "[u]nlike WTO rules, TRIPS-plus provisions in FTAs introduce higher intellectual property protection, in which the government should provide an exclusivity period for the test data done by the originator company, on the grounds of an incentive rationale and considerations of fairness." Wael Armouti, *Evolution of Data Exclusivity for Pharmaceuticals in Free Trade Agreements*, 76 S. CTR. POL'Y BRIEF 1, 5 (2020).

states that it was prepared by the UNCTAD Secretariat "as part of its technical assistance activities in the area of IPRs,"[68] the analysis evidences a lack of attention to the text of the TRIPS Agreement, or the rules of treaty interpretation found in the VCLT.

Rather than starting with text of Article 39.3, interpreted in view of the context and object and purpose of the TRIPS Agreement, the UNCTAD Guide begins with an explicit acknowledgement that the intent of any interpretation should be to "strike[] an appropriate balance between the . . . interests of pharmaceutical product originators on the one hand and the need to ensure access to medicines and competition by product followers on the other hand, *with due regard to* the express language and the canons of interpretation applicable from international law, such as the [VCLT]."[69]

One of the interpretations set out by the UNCTAD Guide as valid was, according to UNCTAD itself, "based on an interpretation of Article 39.3, TRIPS Agreement which seeks to facilitate, *to the greatest possible extent*, the early market entry of generic competitors."[70] In other words, the treaty text comes last, with the primary focus being on trying to formulate a goal-oriented interpretation that strikes the balance that the UNCTAD deems "appropriate," which could be to enable the earliest possible market entry for generic competitors. Such an approach is *wholly inconsistent with the rules of the VCLT*, as adopted by WTO panels and the Appellate Body for over 25 years.

The UNCTAD Guide goes on to declare that the lack of specific definition of the term "new" in the phrase "new chemical entity" indicates that "Members are free to apply the patent concept of novelty,"[71] without considering whether the term "new" in the *context* of Article 39.3 should incorporate the concepts of "new" in Article 27.1. Indeed, as discussed above, this is erroneous.

As for the protection that must be accorded, based on the interpretation of "unfair commercial use," the UNCTAD Guide sets out "three different modes of implementing the unfair commercial use obligation," one of which (i.e., the "misappropriation approach") takes the position that it does not prevent the regulatory authority "from relying on the results of original test data from domestic or foreign approvals when assessing the safety and efficacy of generic competing products, based on claims of bioequivalence ('reliance')."[72] While acknowledging that some take the position that a period of data exclusivity (without permitting reliance) is required by Article 39.3, the UNCTAD Guide responds as follow:

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[68] UNCTAD Reference Guide, *supra* note 67, at iii.

[69] *Id.* at 164 (emphasis added).

[70] *Id.* at 167 (emphasis added).

[71] *Id.* at 165.

[72] *Id.* at 166-67.

> [I]nterpretations of what constitutes "unfair commercial use" vary considerably among WTO members and are possibly influenced by their national priorities. In the related area of pharmaceutical patents, many OECD countries until the 1970s considered the copying of pharmaceutical inventions as entirely fair and beneficial to their industries.[73]

Again, Article 39.3 *does* have a meaning that can be derived through the VCLT's rules of treaty interpretation. It is not up to each WTO Member to determine for itself how it would like to interpret each provision of the TRIPS Agreement, based on their "national priorities." Nor is it relevant that certain countries had historically failed to protect patents on pharmaceutical products and processes. Of course, such a practice today would violate multiple provisions of the TRIPS Agreement, including Article 27.1, which prohibits "discrimination as to . . . the field of technology."[74]

As explained in the UNCTAD Guide, pursuant to the so-called "misappropriation approach," a "drug regulatory authority" ("DRA") would not be prevented:

> from relying on the results of original test data from domestic or foreign approvals when assessing the safety and efficacy of generic competing products, based on claims of bioequivalence ("reliance"). In this connection, the generic producer is not obliged to submit to the DRA clinical data proving the safety and efficacy of his medicament, if he can show that the generic drug is bioequivalent to the originator product. The fact of reliance alone on a domestic or foreign approval and the results of the supporting test data would not of itself constitute unfair use under Article 39 of the TRIPS Agreement.[75]

According to this "approach," the protection would be limited to providing an obligation preventing competitors of the originators of the data from "obtaining the latter's data through unfair commercial means ('misappropriation'), and of using it for unfair commercial advantage, such as to shorten the time and reduce the cost for reverse engineering."[76]

Such an interpretation would render key aspects of Article 39.3 effectively meaningless in view of the protections for trade secrets and other undisclosed information already required by Article 39.1 and Article 39.2.[77] Article 39.2, in particular, already requires that owners of trade

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[73] *Id.* at 171-72.

[74] TRIPS Agreement, *supra* note 1, at art. 27.1.

[75] UNCTAD Reference Guide, *supra* note 67, at 167.

[76] *Id.* (internal citation omitted).

[77] *See* TRIPS Agreement, *supra* note 1, at art. 39.1. *See also* TRIPS Agreement, *supra* note 1, at art. 39.2.

secrets (including commercially valuable data) have the right to prevent such information from being "acquired by, or used by others without their consent in a manner contrary to honest commercial practices."[78] As the Appellate Body explained in the very first Appellate Body Report, *US – Gasoline*, based on the VCLT, an "interpretation must give meaning and effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility."[79]

The UNCTAD Guide notes that the "misappropriation approach...has not survived in recent bilateral or regional free trade agreements between developing and developed countries," opining that this "is a considerable weakening of sovereign power."[80] In reality, the subsequent practice by developed and developing countries alike may instead be viewed as confirmation that the "misappropriation approach" would be inconsistent with Article 39.3 of the TRIPS Agreement.[81]

Acknowledging that countries have interpreted and implemented Article 39.3 in very different ways, Carvalho aptly observes that:

> It is true that legal provisions sometimes are drafted in a manner that calls for a flexible understanding. But there is no record of one legal provision that admits two opposed, and reciprocally destructing, interpretation, like those two mentioned above [i.e., allowing reliance on originator data, and not allowing reliance]. One of those interpretations must be necessarily wrong or, in other words, TRIPS-inconsistent. The TRIPS inconsistent interpretation is the one that admits that authorities rely on originators' data for approving the marketing of similar products without any sort of consideration for the rights and interests of test data originators.[82]

Finally, the UNCTAD Guide confuses the incentives that derive from patent protection with the incentives for data protection, justifying the "misappropriation approach" as appropriate because "most of the approved drugs benefit from patent protection, which already provides drug developers with an important means to recoup their investment into pharmaceutical R&D."[83] Yet, the role of the data protection required pursuant to Article 39.3 is to enable those who invest in achieving *regulatory approval* of a new pharmaceutical or agricultural product with the ability to recoup the tremendous cost of developing *test data* required for such approval, including for products that are not subject to patent

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[78] *Id*. at art. 39.2.

[79] Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996, DSR 1996:I, p. 3.

[80] UNCTAD Reference Guide, *supra* note 67, at 168.

[81] TRIPS Agreement, *supra* note 1, at art. 39.3.

[82] CARVALHO, *supra* note 21, at 264.

[83] UNCTAD Reference Guide, *supra* note 67, at 172.

protection.[84] Patent protection generally serves a different, broader goal of incentivizing development of novel, innovative products and processes in the first place.

Finally, others simply assert – *without even any attempt to explain the basis for such assertion* – that Article 39.3 does not protect test data from being relied upon by governments granting regulatory approval to competitors. For example, in a 2021 paper funded by the WHO's Regional Office for Africa, several professors from Kenya's Daystar University School of Law stated as follows:

> Article 39.3 of the TRIPS Agreement allows countries to determine how to protect test data in the public interest. This provision demands protection from unfair commercial use and does not demand data exclusivity. Countries may therefore incorporate in domestic legislation the right of regulatory authorities to rely on available data to assess new drugs for market entry.[85]

Rather than attempting to interpret the treaty text, the authors of that paper simply assume that when a competitor is permitted to rely on data that has been developed at significant expense by the originator, that such reliance would never constitute "unfair commercial use." They stated that "TRIPS does not define unfair commercial use nor does it provide guidance on how protection can be achieved."[86] The absence of a definition does not, of course, mean that a term can be defined in whatever way a Members wishes. For the reasons set out above, the paper's unsupported assertions about Article 39.3 are incorrect.

2. Protection Against Disclosure

Distinct from its obligation to protect data against "unfair commercial use," Article 39.3 also mandates (in its second sentence) that WTO Members must protect the data against "disclosure."[87] Unlike the former obligation (which does not reference any exceptions), Article 39.3 outlines

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[84] *See* TRIPS Agreement, *supra* note 1, at art. 39.3.

[85] Marion Motari et al., *The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 years After the TRIPS Agreement*, BMC Public Health 21, 490 (March 11, 2021), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y.

[86] *Id.* at Table 3 ("This provision allows countries to determine how to protect test data in the public interest. This provision does not demand data exclusivity, which has the potential of blocking entry of generic versions of patented medicines. Rather, it demands protection from unfair commercial use. TRIPS does not define unfair commercial use nor does it provide guidance on how protection can be achieved. Countries may therefore incorporate in domestic legislation the right of regulatory authorities to rely on available data to assess new drugs for market entry.").

[87] TRIPS Agreement, *supra* note 1, at art. 39.3.

two exceptions to the protection against disclosure.[88] Namely, a Member may allow disclosure "where necessary to protect the public" or when "steps are taken to ensure that the data are protect[ed] against unfair commercial use."[89]

There are few situations where disclosing test data would be "necessary to protect the public." The term "necessary" is used throughout the WTO agreements in the context of exceptions, and the caselaw developed on this term is instructive. As the Appellate Body has explained, in the context of Article XX(d) of the GATT 1994, "the term 'necessary' refers … to a range of degrees of necessity. At one end of this spectrum lies 'necessary' understood as 'indispensable'; at the other end, is 'necessary' taken to mean as 'making a contribution to.'"[90]

In the context of interpreting "necessary" (including under Article XX of the GATT 1994), a challenged measure is generally compared with reasonably available alternative measures that are less trade restrictive (here, less restrictive to IP protection), while making an equivalent contribution to achieving the desired level of protection of the relevant objective (i.e., here, public health).

As set out in Skillington and Solovy, test data appears to have little scientific value beyond demonstrating safety and effectiveness to regulators. There is no evidence that such data would be of assistance to scientists attempting to improve existing pharmaceutical products. The data could be used either (1) to enable a competitor to receive regulatory approval for its own generic product, which is a situation addressed and disciplined by the first sentence of Article 39.3, or (2) to enable members of the public to review data and second guess decisions of the health authorities.[91]

Thus, it follows that a deviation from the obligations of the second sentence of Article 39.3 would require a Member to demonstrate that that, first, a failure to disclose would result in significant harm to the public, and, second, no reasonable alternative exists to protect the public beyond disclosure. Here, the test data that is submitted to health authorities is both voluminous and technical. Releasing the complete test data to the general public would create an opportunity for non-experts to "second guess" the assessment of the regulators. The possibility for the public to benefit from any such public release would be unlikely, given that the expert regulators have already done a careful assessment.

The second exception allows a Member to disclose the information

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[88] *Id.*

[89] *Id.*

[90] Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, adopted 10 January 2001, DSR 2001:I, para. 161.

[91] Skillington & Solovy, *supra* note 7, at 47.

when "steps are taken to ensure that the data are protect[ed] against unfair commercial use." As established previously, this requires Members take steps to ensure that any disclosure will not lead to a competitor's unjust or unfair application or conversion of certain test and other data to make a profit or to obtain a benefit. As set out in Skillington and Solovy:

> The introductory phrase --"In addition'-- indicates that the requirement to prevent disclosure is cumulative, and implies that both protection from unfair commercial use and protection from disclosure are required. Yet, the second exception appears to permit disclosure if protection against unfair commercial use is provided. Thus, in order to read the second exception in a manner that gives meaning to the disclosure prohibition, it must be interpreted as requiring a heightened level of protection against unfair competition before disclosure is permitted, relative to the level required by the first sentence of Article 39.3. In fact, instead of simply stating that a Member "shall protect such data against unfair commercial use," as does the first sentence, the second sentence requires that "steps are taken to *ensure* that the data are protected against unfair commercial use" (emphasis added). Interpreting this provision pursuant to Vienna Article 31, one finds that . . . a government must implement additional regulations to benefit the originator of the data that would not be necessary if the data were not disclosed. Perhaps this would take the form of a much longer period of market or data exclusivity for the originator if the data are disclosed.[92]

Thus, to the extent that a regulator publishes a summary of clinical trials online, such information should still be protected against "unfair commercial use."

III. CLARIFICATION AND EXPANSION OF TRIPS AGREEMENT DISCIPLINES THROUGH FREE TRADE AGREEMENTS

While treaty provisions are susceptible of a fixed interpretation which, of course, does not change based on the motivations and objectives of each individual party, WTO Members are nonetheless granted some discretion in determining *how* best to implement the substantive obligations of the TRIPS Agreements. Specifically, Article 1.1 (third sentence) provides that Members are "free to determine the appropriate method of implementing the provisions of [the TRIPS] Agreement within their own legal system and practice." In addition, Article 1.1 (second sentence) provides that "[m]embers may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement."

In the context of protecting test data under Article 39.3 of the TRIPS Agreement, Article 1.1 of the TRIPS Agreement thus clarifies that

[92] *Id.* at 48.

Members may choose to (i) extend data protection to types of data that go beyond what is required by that provision, or in circumstances not meeting those listed in Article 39.3; and (ii) provide substantive protection that goes beyond what is strictly required under Article 39.3, with respect to protection against "unfair commercial use" and "disclosure." To take an example, WTO Members may choose to protect data submitted for approval of pharmaceutical products that do not utilize a "new chemical entity," such as approval for new uses of previously approved products. Providing such additional protection would not "contravene the provisions of [the TRIPS] Agreement," within the meaning of Article 1.1.

WTO Members have entered into a number of bilateral and multilateral trade agreements that clarify or expand upon the obligations in the TRIPS Agreement, including with respect to data protection. Such countries have modified their laws or practices in order to comply with those additional FTA obligations, or they have committed to maintain their existing regimes in order to maintain compliance.

The WTO Secretariat, in 2014, calculated that 116 of 245 active FTAs contained provisions addressing specific types of IP.[93] Additional FTAs are entered into on a regular basis. Regulatory test data protection is an increasingly standard addition to these FTAs.

A. Minimum Periods of Data Exclusivity

The TRIPS Agreement does not explicitly outline the precise manner in which test data should be protected, or the minimum period of time during which such protection should be provided. That said, there are some WTO Members who, upon their accession to the WTO, made certain commitments to provide such protection for a minimum period of time, including China for 6 years (accession on December 11, 2001) and Saudi Arabia for five years (accession on December 11, 2005). [94] As discussed above, the proper interpretation of Article 39.3 dictates that WTO Members should provide protection that is long enough to enable a manufacturer to at least recoup its investments in producing the test data.

FTAs with data protection provisions often clarify a time period during which the originator's data may not be relied upon in order to provide marketing approval for a competitor, a degree of specificity that is missing from Article 39.3 of the TRIPS Agreement.[95]

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[93] Raymundo Valdés & Maegan McCann, "Intellectual Property Provisions in Regional Trade Agreements: Revision and Update," WTO Staff Working Paper, No. ERSD-2014-14 7 (Sept. 23, 2014), http://www.wto-library.org/content/papers/25189808/169.

[94] Report of the Working Party on the Accession of China, WT/ACC/CHN/49, (adopted Oct. 1, 2001), at 59, para. 284; Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization, WT/ACC/SAU/61, (adopted Nov. 1 2005), at 84–85, para. 261.

[95] *But see* Comprehensive Economic Partnership Agreement, Indonesia-EFTA (Dec. 16, 2018). The EFTA-Indonesia FTA declines to define the period of protection. Instead, it

For instance, the EU-Canada Comprehensive Economic and Trade Agreement ("CETA") requires parties to provide at least six years of protection before a third party can apply for marketing approval based on data from the reference product, and at least eight years before marketing approval may be granted.[96] With respect to FTAs entered into by the United States, under, e.g., the U.S.-Singapore FTA, U.S.-Chile FTA, and U.S.-Australia FTA, third parties cannot be granted marketing approval for at least five years following approval of the original product.[97] In the most recent major U.S. FTA, the U.S.-Mexico-Canada Agreement ("USMCA"), the term of protection is likewise set at five years from the date of marketing approval in the territory of the Party.[98] To take another example, Article 11.11.2 of the Switzerland-China FTA provides that:

> The Parties shall prevent applicants for marketing approval for pharmaceuticals, including chemical entities and biologics, and agricultural chemical products from relying on, or referring to, undisclosed test data or other data submitted to the competent authority by the first applicant for a period, counted from the date of marketing approval, of at least six years for pharmaceuticals and for agrochemical products.[99]

In some FTAs, extensions on protection may be granted if the originator receives authorization for one or more new therapeutic indications (for pharmaceuticals) or minor uses (for agricultural chemicals).[100]

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requires that parties provide data exclusivity for a "period of time defined in the domestic laws and regulations." EFTA-Indonesia FTA, Annex XVII, Article 6.2(b). The flexibility granted by that FTA in defining the length of the period of protection does not, however, justify a Party's derogation from the obligation to implement a data exclusivity regime in domestic law.

[96] Comprehensive Economic and Trade Agreement Between Canada and the European Union ("CETA") (Jan. 14, 2014) Article 20.29(2).

[97] United States - Singapore Free Trade Agreement, art. 16.8(1), May 6, 2003, Office of the U.S. Trade Representative [hereinafter U.S.-Singapore FTA]; United States - Chile Free Trade Agreement, art. 17.10(1), June 6, 2003, Office of the U.S. Trade Representative [hereinafter U.S.-Chile FTA]; United States - Australia Free Trade Agreement, art. 17.10(1)(a), May 18, 2004, Office of the U.S. Trade Representative [hereinafter U.S.-Australia FTA].

[98] United States-Mexico-Canada Agreement, art. 20.48(a), July 1, 2020, Office of the U.S. Trade Representative [hereinafter USMCA].

[99] Free Trade Agreement between The Swiss Confederation and The People's Republic of China, art. 11.11.2, July 6, 2013, State Secretariat for Economic Affairs [hereinafter Switzerland-China FTA].

[100] *See, e.g.*, Free Trade Agreement Between the EFTA States and Georgia, Annex XV, Art. 6, June 27, 2016; Free Trade Agreement Between the EFTA States and Ukraine, Annex XIII, Art. 5, June 24, 2010; Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part, Sept. 1, 2021, Article 187; Free Trade Agreement Between the EFTA States and Bosnia and Herzegovnia, Annex VII, Art. 6, June 24, 2013; Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic

Some FTAs, including the USMCA, provide that, to the extent a party (here, the U.S., Mexico, or Canada) can (pursuant to its own domestic law) rely on the prior marketing approval of the product in another territory when performing its own evaluation for marketing approval, that party may not allow an entity to rely on that prior marketing approval for "at least five years from the date of marketing approval of the new pharmaceutical product in the territory of that Party."[101] A similar clause appears in the U.S.–Australia FTA, among other agreements.[102] As noted above, this limitation (but not the minimum period of protection) is already implicit from a proper interpretation of Article 39.3 of the TRIPS Agreement.

Certain FTAs clarify that the period of data exclusivity is *independent of the term of any patent covering the relevant pharmaceutical product*. For example, the U.S.-Korea FTA provides:

> when a product is subject to a system of marketing approval in the territory of a Party in accordance with paragraph 1 or 2 and is also covered by a patent in that territory, the Party may not alter the term of protection that it provides in accordance with those paragraphs in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in those paragraphs.[103]

Other agreements, including the USMCA, contain a similar provision.[104]

This is in line with a proper interpretation of the TRIPS Agreement, itself, in which the substantive rights that must be accorded to patents, in Part II, Section 5, are separate from the substantive rights that must be accorded to test data, in Part II, Section 7. Each protects a different type of subject matter, creating separate incentives to develop inventions and test data for regulatory approval, respectively. There is no exception for protection of test data that stems from expiration (or non-existence) of a related patent. According to industry reports, there are some countries that nevertheless end data protection upon expiration of a related patent.[105]

B. Protectable Subject Matter

Certain FTAs seek to clarify the meaning of the term "new chemical entity" found in Article 39.3 of TRIPS. For example, the EU –

Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part, Article 251, Jan. 26, 2018.

[101] USMCA, *supra* note 98, at art. 20.48.1(b).

[102] U.S.-Australia FTA, *supra* note 97, at art. 17.10(c).

[103] Free Trade Agreement between the United States of America and the Republic of Korea, art. 18.9.4, March 15, 2012, Office of the U.S. Trade Representative.U.S.-Korea FTA, Article 18.9.4 [hereinafter U.S.-Korea FTA]

[104] USMCA, *supra* note 98, at art. 20.51.

[105] *See, e.g.*, PhRMA's 2022 Special 301 Submission, *supra* note 5, at 160 (noting "if a product is patented in Turkey, RDP ends when that patent expires, even if this is prior to the end of the six-year RDP term.").

Colombia/Peru Trade Agreement provides that a new chemical entity is:

> one which has not been previously approved *in the territory of the Party* for its use in a pharmaceutical or chemical agricultural product, pursuant to its domestic legislation. Accordingly, the Parties need not apply this Article with respect to pharmaceutical products that contain a chemical entity that has been previously approved in the territory of the Party.[106]

Similarly, the USMCA provides protection for data submitted as a condition for granting marketing approval for a "new pharmaceutical product," which is defined as "a pharmaceutical product that does not contain a chemical entity that has been previously approved *in that Party*."[107] Under this definition, chemical entities do not need to make their international debut in a WTO Member to merit test data protection. Instead, the chemical entities must be "new" only to the market of the Member for which the originator is seeking regulatory approval. As discussed above, this clarification is consistent with a proper interpretation of what Article 39.3 of the TRIPS Agreement already requires.[108]

Additionally, several FTAs clarify that the "pharmaceuticals" covered by the protection include biological entities.[109] Again, as explained above, this is already inherent in the TRIPS Agreement, through the use of the broad term "chemical entity."[110]

Finally, certain FTAs have expanded the scope of the protection term *beyond what is required under the TRIPS Agreement*. For example, the U.S.-Korea FTA provides, in addition to the 5 year period of protection for new chemical entities, a 3 year period of protection for "a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product."[111] This test data may refer to new uses, as well as a new combination or new dosage form. To take another example, the U.S.-Australia FTA mandates at least three years of protection for data "which is essential to the approval of a pharmaceutical product," even if such data is not for a "new product" (defined as one that does not contain a chemical entity that has been previously approved for marketing in the party).[112] Again, such protection,

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[106] The EU Colombia-Peru Trade Agreement, Aug. 1, 2013, art. 231.3 (emphasis added).

[107] USMCA, *supra* note 98, at art. 20.49 (emphasis added).

[108] *See supra* Part II.B.

[109] Art 5(a) Central American EFTA FTA (mentioning only pharmaceutical without restricting it to chemical entity); Art 6(1), Annex VI, Montenegro-EFTA FTA, and Art 6, Annex VIII, Bosnia and Herzegovina-EFTA FTA.

[110] *See supra* Part II.B.

[111] U.S.-Korea FTA, *supra* note 103, at art. 18.9.2.

[112] U.S.-Australia FTA, *supra* note 97, at art. 17.10(2). *See also* United States – Jordan Free Trade Agreement art. 22, n. 10, Dec. 17, 2001, Office of the U.S. Trade Representative [hereinafter U.S.-Jordan FTA] ("It is understood that protection for 'new chemical entities'

which does not involve "new chemical entities," is not required by the TRIPS Agreement.

C. Patent Linkage

Several U.S. FTAs introduce provisions "linking" regulatory approval with the protection period of an originator's patent. Under such a regime, drug regulatory authorities cannot approve a generic version of a medicine that is under patent without the consent of the patent holder. An effective patent linkage system requires an updated database that documents information on the patent status of drugs that have received marketing approval, such as the U.S. FDA's Orange Book, along with a mechanism to notify the patent owner of any attempt by a generic competitor to enter the market. This type of linkage requirement is focused more on providing for effective patent protection rather than the data protection required by Article 39.3 of the TRIPS Agreement.

The patent linkage requirements differ significantly among different FTAs. The U.S.-Jordan FTA, for example, requires only that a Party notify the patent holder "of the identity of any third party requesting marketing approval effective during the term of the patent."[113] The U.S.-Korea FTA goes further by including the additional requirement that a Party must implement a mechanism that would prevent a third party from gaining marketing approval "without the consent or acquiescence of the patent owner during the term of a patent."[114] The USMCA contains similar linkage requirements, requiring the existence of "procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measure" to resolve disputes concerning the validity or infringement of an applicable patent.[115]

IV. REPORTED DEFICIENCIES IN TEST DATA PROTECTION, AND IMPLICATIONS THEREOF

As discussed in Part II, above, the 164 Members of the WTO have committed to provide a minimum level of substantive protection for various forms of intellectual property, including certain test data submitted for regulatory approval of pharmaceutical or agricultural chemical products. Many WTO Members have either implemented or reformed their domestic legislation in an attempt to comply with these obligations. In practice, WTO Members often fall short of meeting their IP-related treaty commitments.

With particular respect to Article 39.3, the obligation to protect the data falls upon the government itself, as it is the Member that receives the

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shall also include protection for new uses for old chemical entities for period of three years.").

[113] U.S.-Jordan FTA, *supra* note 112, at art. 4.23(b).

[114] U.S.-Korea FTA, *supra* note 103, at art. 18.9.5(b).

[115] USMCA, *supra* note 98, at art. 20.5.1.

test data and has an obligation to protect it against unfair commercial use and disclosure. To provide legal certainty that the protection will be provided, the obligations in Article 39.3 should be implemented through a written law or regulation, and not left to the discretion of individual regulators.[116]

Because the WTO Members that most frequently fail to provide the protections required by Article 39.3 are developing countries, the result is that the incentives to generate data for conditions found predominately in such countries are greatly diminished, along with lower incentives to develop data for pharmaceuticals that would be marketed around the globe. This reality (and the balance that intellectual property rights are intended to create between development and use, per Articles 7 and 8.1 of the TRIPS Agreement) is seemingly not fully considered by those that advocate that test data protection has a "negative impact" in developing countries, based on their view that such exclusivity delays the entry of "cheap generic products" in the market.[117]

Among the key deficiencies in pharmaceutical test data protection identified through industry submissions are the following:

(1) Failure to protect data against "unfair commercial use," by allowing a second entrant to rely on the data provided to a government by the developer of the data before providing the reasonable opportunity to recoup the investment;
(2) Failure to protect data with respect to all types of "new chemical entities," through an unduly narrow interpretation of the term "chemical entity"; and
(3) Failure to protect data with respect to "new chemical entities," through an unduly narrow interpretation of the term "new."

In this section, we consider each of these deficiencies, in turn, and recall why they would appear to result in violations of the WTO Members' international obligations.

A. Failure to Protect Against "Unfair Commercial Use"

Presumably based on a flawed interpretation of the term "unfair commercial use," some WTO Members take the position that there is nothing preventing them from providing marketing approval to a generic producer through reliance on undisclosed test data submitted by the originator of test data to that government (or to another country's government), regardless of how little time may have passed since the

[116] *See* CARVALHO, *supra* note 21, at 267 (stating that the "implementation of Article 39.3 does require the enactment of national laws or regulations (unless a certain WTO Member does not require that products be approved prior to their commercialization).").

[117] Armouti, *supra* note 67, at 5. *See also* Yu, *supra* note 8, at 5.

originator submitted its data. Yet, for the reasons discussed above, such an approach would violate the obligation in Article 39.3 to protect such data against "unfair commercial use."

To recall, enabling a competitor to free ride on the investment, time, and effort that goes into producing test data submitted to a government – before allowing passage of a period of time capable of enabling recoupment of such investment – is both "commercial" (as the competitor will benefit commercially from that reliance) and "unfair."

Beginning with Brazil, while Law 10.603/02 appears to provide 5 to 10 years of data exclusivity for veterinary pharmaceuticals and agricultural chemicals,[118] in practice Brazil reportedly provides no period of data exclusivity for pharmaceuticals for humans, contrary to the terms of Article 39.3 of the TRIPS Agreement.[119] Thus, competitors are able to receive marketing approval for pharmaceutical products from the Brazilian government by relying on test and other data submitted by the originators.[120] There is nothing in Article 39.3 that permits an interpretation that would limit the term "pharmaceutical" products to cover only veterinary pharmaceuticals.

Turning to China, upon accession to the WTO, it agreed to provide at least six years of data exclusivity for all new pharmaceutical and agrochemical products.[121] Moreover, China is party to a bilateral trade agreement with Switzerland, which also requires six years of data exclusivity for pharmaceuticals and agricultural chemical products.[122] In order to meet these obligations, China promulgated the Drug Administration Law ("DAL") and Drug Registration Regulation ("DRR"), which are administered by the National Medical Products Administration ("NMPA"). Both laws provide for a six-year period of protection, against "improper commercial use," for test data submitted in the course of requesting regulatory approval of pharmaceutical products containing a new chemical ingredient.[123] Nevertheless, the biopharmaceutical industry reports that, in practice, no foreign drug producers have received data exclusivity

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[118] Law No. 10,603 (Dec. 17, 2002).

[119] *See* Office of the U.S. Trade Representative 2022 Special 301 Report [hereinafter "USTR 2022 Special 301 Report"], at 66, https://ustr.gov/sites/default/files/IssueAreas/IP/2022%20Special%20301%20Report.pdf. *See also* PhRMA's 2022 Special 301 Submission, *supra* note 5, at 176; Biotechnology Innovation Organization, 2022 Special 301 Submission to the U.S. Trade Representative [hereinafter "BIO's 2022 Special 301 Submission"], Jan. 31, 2022, at 21.

[120] PhRMA's 2022 Special 301 Submission, *supra* note 5.

[121] Report of the Working Party on the Accession of China, WT/ACC/CHN/49 (Oct. 1, 2001), WT/ACC/CHN/49 para. 284.

[122] Switzerland-China FTA, *supra* note 99, at art. 11.11.

[123] Na Li, Xiang Yu, and Michael Pecht, *Position and enforcement practice of the People's Republic of China's pharmaceutical data exclusivity protection*, 10 DRUG DES DEVEL THER. 2015 (June 2016).

from China,[124] and that China permits follow-on applicants to rely on the data submitted by the original drug manufacturer to the NMPA during the data protection term.[125] Notably, and presumably in response to these reported deficiencies, the January 15, 2020 U.S.-China "Phase One" Trade Agreement contains general language requiring "effective protection and enforcement of" *inter alia* "undisclosed test or other data submitted as a condition of marketing approval."[126]

Similarly, the European Commission notes that, despite a law on the books that appears to provide for regulatory test data protection in Russia for six years from the date of marketing authorization in Russia, in reality, Russia has granted marketing approval to generic pharmaceuticals (during what is supposed to be the term of protection) by relying on the data submitted by originators.[127] Specifically, in 2012, as part of its accession to the WTO, Russia enacted Article 18 of Federal Law No. 61-FZ prohibiting follow-on manufacturers from relying on clinical test data submitted by the original manufacturer, without the manufacturer's consent, for six years.[128] Russia has since adopted the position, however, that rules on the registration of new medicines for the Eurasian Economic Union, of which it is a part, supersede Federal Law No. 61-FZ; these rules do not provide for any period of test data protection.[129] As a result, a generic manufacturer secured marketing approval in Russia during the six-year period in which the original manufacturer's test data should have been protected under Federal Law No. 61-FZ.[130]

As a final example, the Kingdom of Saudi Arabia indicated, upon its 2005 accession to the WTO, that it would provide at least five years of data exclusivity for all new pharmaceutical and agrochemical products, and it put into place a regulation that it stated would achieve this commitment.[131] However, in reality, since 2016, the Saudi Food and Drug Agency has reportedly granted marketing approval to domestic companies relying on another company's undisclosed test or other data for pharmaceutical

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[124] BIO's 2022 Special 301 Submission, *supra* note 119, at 22.

[125] PhRMA's 2022 Special 301 Submission, *supra* note 5, at 66.

[126] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, Section C at 1-5.

[127] European Commission 2021 Report on The Protection and Enforcement of Intellectual Property Rights in Third Countries, 27, https://trade.ec.europa.eu/doclib/docs/2021/april/tradoc_159553.pdf [hereinafter "European Commission 2021 Report"]. *See also* USTR 2022 Special 301 Report, *supra* note 119 at 61.

[128] PhRMA's 2022 Special 301 Submission, *supra* note 5, at p. 150.

[129] *Id.*

[130] *Id.*

[131] Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization, WT/ACC/SAU/61 (Nov. 1, 2005), para. 261; Article 5 of a Council of Ministers' Trade Secrets Protection Regulation (decision No. 50, dated 25/2/1426 H, April 4, 2005).

products, despite the protection promised by Saudi regulations.[132] Not only has there been no redress for the companies whose data was not protected but, according to the U.S. Government, the Saudi government "reportedly awarded national tenders to some of these domestic companies" who unfairly relied on another company's undisclosed data.[133]

B. Erroneous Interpretation of "Chemical" in "Chemical Entity"

Some countries appear to take an unduly narrow interpretation of the term "chemical" in the phrase "chemical entities," such that they exclude biologics from protection. As explained above, as biologics (like all matter) are composed of chemicals, excluding them from coverage constitutes a violation of Article 39.3 of the TRIPS Agreement.

As noted above, biologics are a class of drugs based on proteins with therapeutic effect; they are large protein molecules.[134] They are produced in biotechnological processes via genetically modified cells of microorganisms – common for cancer treatment, for example. They require extensive quality assurance testing for potency, purity, and quality, often far beyond what is required for small-molecule drugs. [135]

Given the decision taken by some countries to exclude biologics from data protection, it is ironic that, compared to small molecule drugs, data protection for biologics (i.e., large protein molecules) may be relatively *more important* for properly incentivizing development and approval of new medicines. This is due, in part, to the particularly extensive testing required for biologics, and the fact that patent protection for biologics is often less robust. To wit, due to the nature of the technology, patents on biologics are often process patents or narrowly drawn product patents, which may be more susceptible to workarounds by biosimilars.[136]

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[132] Office of the U.S. Trade Representative 2021 Special 301 Report ("USTR 2021 Special 301 Report"), p. 57, https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf. *But see* USTR 2022 Special 301 Report, *supra* note 119 at 10 (noting USTR continues to monitor such approvals, which Saudi Arabia last granted in Oct. 2020).

[133] USTR 2021 Special 301 Report, *supra* note 132 at 57.

[134] *See, e.g.*, Kathy Oxtoby, *How Biologics Have Changed the Rules for Pharmacuetical Industry*, CHEMISTRY WORLD (May 7, 2019), https://www.chemistryworld.com/molecule-to-market/how-biologics-have-changed-the-rules-for-pharma/3010301.article.

[135] *Id.* (explaining that "biologics come at a price, as they are more expensive than synthesised chemical treatments to produce, to research, and require greater monitoring of patients" (internal quotations omitted)).

[136] *See generally* The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics, BIO White Paper, (July 2013), at 11 ("the scientific complexity of, and inability to objectively characterize, most biological products also translates into greater commercial uncertainty for innovators and the investors that support them. Specifically, the scientific differences between the biologic and biosimilar products create uncertainty as to whether the innovator's patents will cover the biosimilar product"), 19 ("The combined effect of these changes in legal standards and examination

Indeed, the biopharmaceutical industry has often argued that data protection for biologics should be even stronger than for small molecule drugs, based on the understanding that a twelve year period of data protection would strike the right balance between maintaining incentives and allowing for additional competition by biosimilars.[137] This is the standard under U.S. law, per the Biologics Price Competition and Innovation Act of 2009,[138] which exceeds the standard five year protection for new drugs in the United States.[139]

Chile serves as an example of a WTO Member that provides five years of data protection for small molecule drugs, but does not provide data protection for biological medicines, despite its commitments under the TRIPS Agreement and the U.S.-Chile FTA.[140] According to the European Commission's 2021 Report on IP Protection in Third Countries, Turkey is also a country that, according to stakeholders, does not provide test data protection for biologics.[141] Further, industry reports indicate that Mexico does not provide test data protection for biologics, despite the obligations under both the TRIPS Agreement and the USMCA; industry has also explained that the Mexican government continues to make a distinction between biologics and other drugs for purposes of considering test data protection.[142]

C. Erroneous Interpretation of "New" in "New Chemical Entity"

As explained above, for a country to determine whether "chemical entities" are "new," within the meaning of Article 39.3, it must find only that the chemical entity at issue has not previously been approved for regulatory approval *in that country*. There is no patent-like novelty standard embedded in Article 39.3. Yet, some countries appear to forego protection of valuable test data based on an unduly and erroneously narrow interpretation of "new."

Beginning with the example of India, the U.S. Government notes

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practices has made it increasingly difficult for an innovator to secure patent claims that grant broad rights beyond a specific protein sequence that was tested and evaluated."). Available at https://www.bio.org/sites/default/files/legacy/bioorg/docs/TPP%20White%20Paper%20_2_.pdf.; Yu, *Data Exclusivities*, *supra* note 21 at 689 (noting that "commentators have noted the challenge in obtaining sufficient protection for these products through the patent system").

[137] *See, e.g.*, The Trans-Pacific Partnership and Innovation in the Bioeconomy: The Need for 12 Years of Data Protection for Biologics, *supra* note 136.

[138] Biologics Price Competition and Innovation Act, § 7002 (amended 2020).

[139] 21 U.S.C.S § 355(b)(1).

[140] BIO's 2022 Special 301 Submission, *supra* note 119, at 20.

[141] European Commission 2021 Report, *supra* note 127 at 30.

[142] PhRMA's 2022 Special 301 Submission, *supra* note 5, at p. 197. *See also* BIO's 2022 Special 301 Submission, *supra* note 119, at pp. 20-21 (noting Mexico's failure to provide regulatory data protection consistent with obligations under the USMCA and urging USTR to ensure protection for biologics).

widespread concern that India lacks "an effective system for protecting against unfair commercial use, and unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for … products."[143] Among other deficiencies in India's regime for protecting regulatory test data, Indian regulators may rely on approval by another country,[144] implicitly based on the view that the chemical entities are not "new" once approved abroad.

China has also adopted an unduly narrow interpretation of "new," defining it to mean "new to the world."[145] Accordingly, China, which currently does not provide any regulatory data protection, would appear to extend such protection to chemical entities only "when they have never been marketed in any country."[146] The European Commission points out that this practice "would de facto discriminate against foreign products."[147]

In Colombia, the health agency reportedly does not classify a chemical entity as "new" if it has "some 'structural similarity' or 'analogy' "with active ingredients of medicines already approved in Colombia."[148] Yet, there is no basis for interpreting "new" in this narrow manner, as it should be based on whether the particular chemical entity at issue has been previously approved in Colombia. Given uncertainty as to whether test data protection will be accorded for a new drug or biologic that has not been previously approved in Colombia, the incentives for developing and submitting such data are consequently diminished.

In Argentina, the Confidentiality Law reportedly provides protection for chemical entities only if they make their debut in Argentina, as the regulatory body is able to approve a similar or identical product based on regulatory approval of an innovator's product in another country.[149] Implicitly, that is because such chemical entities would not be considered "new chemical entities." Yet, per the correct interpretation of Article 39.3 set out above, the term "new" is understood in view of the regulatory system of the Member receiving an application for approval, not the status in other countries.

Malaysia generally provides data exclusivity for undisclosed pharmaceutical test data submitted for regulatory approval to its own

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[143] USTR 2022 Special 301 Report, *supra* note 119 at 54. *See also* European Commission 2021 Report, *supra* note 127 at 25.

[144] PhRMA's 2022 Special 301 Submission, *supra* note 5, at 92 (citing Rules 75 and 80 of the Ministry of Health and Family Welfare, The New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf).

[145] *Id.*, at p. 66 & n. 145 (citing a 2018 proposal by the NMPA to extend full regulatory data protection only to products "new to the world").

[146] European Commission 2021 Report, *supra* note 127 at 19.

[147] *Id.*

[148] BIO's 2022 Special 301 Submission, *supra* note 119, at 20.

[149] *Id.* at 21; European Commission 2021 Report, *supra* note 127 at 35.

authorities. That said, its regulations limit the availability and term of protection provided to pharmaceuticals that are first introduced in another country, again implicitly based on an unduly narrow interpretation of the term "*new* chemical entities." For example, Malaysia's relevant directive is limited by paragraph 4.2 thereof, which reads:

> An application for Data Exclusivity shall only be considered if the application in Malaysia for:
>
> (i) New drug product containing a New Chemical Entity is made within eighteen (18) months from the date the product is first registered or granted marketing authorization; and granted Data Exclusivity / Test Data Protection in the country of origin or in any country, recognized and deemed appropriate by the Director of Pharmaceutical Services.[150]

Thus, under this regime, originators are reportedly required to submit the new drug application in Malaysia within eighteen months after having been registered in another country, in order to receive any protection.[151] Additionally, Malaysia's regulations start the term of protection from the date of the first approval, even if that approval was provided by a foreign country.[152] Therefore, the only way an originator can receive the full term of protection generally accorded is if it first introduces the drug into the Malaysian market.[153]

To take a final example, the European Commission has previously pointed out that Ukraine had made "eligibility for test data protection dependent on the filing of the first marketing authorization in Ukraine within two years after a marketing authorization has been granted anywhere in the world."[154] This again implicitly depended on an erroneous interpretation of the word "new" in Article 39.3, as meaning something other than "new" in the regulatory system of the country required to provide the protection.

V. CONCLUSION

As detailed above, while an interpretation of the TRIPS Agreement pursuant to the Vienna Convention can yield a single "correct" interpretation of Article 39.3 of the TRIPS Agreement, those WTO Members, academics and others that advocate for "flexible" interpretations

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[150] Directive on Data Exclusivity in Malaysia, under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984, No. 2 (2011).

[151] European Commission 2021 Report, *supra* note 127 at 44; PhRMA's 2022 Special 301 Submission, *supra* note 5, at 118–19.

[152] PhRMA's 2022 Special 301 Submission, *supra* note 5, at 119; BIO's 2022 Special 301 Submission, *supra* note 119, at 22.

[153] *Id.*

[154] European Commission 2021 Report, *supra* note 127 at 31.

take very different positions. Those interpretations are often based on purpose-driven analyses that interpret the treaty obligations in a way that best suits certain policy goals, rather than the holistic interpretation of the ordinary meaning of the treaty terms in context and in light of the object and purpose, as required by the VCLT and WTO panel and Appellate Body jurisprudence.

Beyond the exercise in treaty interpretation performed above, one may also look to practical application to consider whether effective data protection, in reality, satisfies the dual objectives in the TRIPS Agreement of "promotion of technological innovation" and "dissemination of the technology" in order to achieve "the mutual advantages of producers and users of technological knowledge and in a manner conduce to social and economic welfare, and to a balance of rights and obligations."[155] In fact, what we have seen from the past several decades is that, for those countries that provide data protection for pharmaceutical products (including protection that goes beyond the scope of Article 39.3), the result has been greater entry into the marketplace of new pharmaceuticals, and new approved uses of earlier-approved medicines.

As has been the case for many other provisions of the WTO Agreements since 1995, Members (and stakeholders) should consider taking advantage of the WTO dispute settlement mechanism to motivate better adherence to the disciplines created by Article 39.3, particularly against those Members that do not provide any protection against reliance on an originator's data. In the meantime, given the lack of any dispute settlement proceedings related to ongoing violations of Article 39.3, WTO Members will likely continue to make use of FTAs to both clarify their understanding of the requirements of the TRIPS Agreement, as well as to expand those disciplines.

[155] TRIPS Agreement, *supra* note 1, at art. 7.