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Research Report

The comprehensive and progressive agreement for the trans-pacific partnership: Data exclusivity and access to biologics

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Research
Paper

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The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership: Data Exclusivity and Access to Biologics

Zelege Temesgen Boru




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THE COMPREHENSIVE AND PROGRESSIVE AGREEMENT FOR THE TRANS-PACIFIC PARTNERSHIP: DATA EXCLUSIVITY AND ACCESS TO BIOLOGICS

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SOUTH CENTRE

MARCH 2020

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ABSTRACT

The test data rule concerning biological medicines (hereafter biologics) has been suspended from the scope of application of the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership (CPTPP). While the suspension is commendable from the general standpoint of access to medicines and biologics in particular, the suspended provision may not provide assurance for the Parties to the CPTPP that they can rely on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to promote access to biologics.² In part this is because the Parties may end the suspension *if and when* they choose to do so. Simply put, the agreement does not promise that the suspended provision will remain suspended; rather, the Parties may revive the provision as originally negotiated under the Trans-Pacific Partnership (TPP) Agreement. The provision, if revived, may inhibit the Parties from implementing an obligation to ensure access to biologics, medicines that target chronic and rare ailments like cancer, clotting factors and several others.

Against this backdrop, this research paper focuses on the test data rule relating to biologics as negotiated under the TPP. In particular, it explores whether the CPTPP Parties would be able to use TRIPS flexibilities effectively to promote access to biologics, as advanced by international human rights instruments, in particular the International Covenant on Economic, Social and Cultural Rights (ICESCR). The paper also provides potential responses to the question of whether the test data rule deters the realization of access to biologics. In response, the author has determined that the rule on test data can limit access to biologics, as it would delay the entry of affordable biologics (biosimilars) into markets.

La mise en œuvre de la disposition relative aux données d'essai concernant les médicaments biologiques contenue dans l'Accord global et progressif de Partenariat transpacifique a été suspendue. Si cette suspension apparaît souhaitable en vue de favoriser l'accès aux médicaments et aux produits biologiques en particulier, elle pourrait priver les parties à l'accord de la possibilité de bénéficier des flexibilités de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) et, par conséquent, de favoriser effectivement cet accès. Cela s'explique en partie par le fait que les parties peuvent décider de revenir sur cette suspension si et quand elles le souhaitent. En termes simples, l'accord ne garantit pas la suspension définitive de cette disposition, qui pourra être rétablie par les parties ainsi qu'elle a été négociée à l'origine dans le cadre de l'accord de partenariat transpacifique. Or, ce rétablissement est susceptible de les empêcher de mettre en œuvre l'obligation de garantir l'accès aux produits biologiques, aux médicaments qui ciblent des maladies chroniques et rares comme le cancer, les déficits en facteurs de coagulation et d'autres maladies.

Cette étude propose une analyse de la disposition relative aux données d'essai relatives aux produits biologiques telle qu'elle a été négociée dans le cadre de l'Accord global et progressif de Partenariat transpacifique. Elle examine en particulier si les parties à l'Accord pourraient efficacement recourir aux flexibilités de l'ADPIC pour faciliter l'accès aux produits biologiques, comme le prévoient les instruments internationaux relatifs aux droits de l'homme, en particulier le Pacte international relatif aux droits économiques, sociaux et culturels. Elle

² The Trade-Related Aspects of Intellectual Property Rights is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO), which was signed on 15 April 1994. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

tente d'apporter des réponses à la question de savoir si cette disposition a pour effet de nuire à la réalisation de l'objectif de faciliter l'accès aux produits biologiques et conclut au demeurant que la disposition relative aux données d'essai peut contribuer à limiter l'accès aux produits biologiques en retardant l'entrée de produits biologiques abordables (biosimilaires) sur les marchés.

La norma de los datos de pruebas relativa a los medicamentos biológicos (en adelante "biológicos") se ha suspendido del ámbito de aplicación del Tratado Integral y Progresista de Asociación Transpacífico (TIPAT). Aunque la suspensión es encomiable desde el punto de vista del acceso a los medicamentos en general y a los biológicos en particular, puede que la disposición suspendida no ofrezca garantías a las Partes en el TIPAT de que puedan depender de las flexibilidades previstas en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) para promover el acceso a los biológicos. Esto se debe, entre otras cosas, a que las Partes pueden poner fin a la suspensión cuando decidan hacerlo. Dicho sencillamente, el Acuerdo no promete que la disposición suspendida permanecerá suspendida; en vez de eso, las Partes pueden restablecer la disposición tal como se negoció originalmente en el marco del Acuerdo de Asociación Transpacífico (TPP, por sus siglas en inglés). La disposición, de restablecerse, puede impedir a las Partes la posibilidad de implementar una obligación de asegurar el acceso a los biológicos, medicamentos que actúan ante enfermedades crónicas y raras como el cáncer, factores de coagulación y algunos otros.

En este contexto, este documento de investigación se centra en la norma de los datos de pruebas relativa a los biológicos tal como se negoció en el marco del TPP. En particular, se examina si las Partes en el TIPAT serían capaces de utilizar eficazmente las flexibilidades del ADPIC para promover el acceso a los biológicos, como se defiende en los instrumentos internacionales de derechos humanos, concretamente en el Pacto Internacional de Derechos Económicos, Sociales y Culturales. En el documento también se proporcionan posibles respuestas a la pregunta de si la norma de los datos de pruebas impide la realización del acceso a los biológicos. En su respuesta, el autor ha determinado que la norma de los datos de pruebas puede limitar el acceso a los biológicos, ya que demoraría la entrada de biológicos (biosimilares) asequibles en los mercados.

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1. INTRODUCTION

The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership Agreement (CPTPP) is a Free Trade Agreement (FTA) that was negotiated for more than a year by 11 countries in Asia, North and South America and Oceania.³ In particular, the agreement brings together Pacific Rim countries, including Vietnam, Singapore, Peru, New Zealand, Mexico, Malaysia, Japan, Chile, Canada, Brunei and Australia.

Although these nations negotiated this agreement, they did so as “a way forward to implement” the Trans-Pacific Partnership (TPP) Agreement, which was signed in Auckland, New Zealand on 4 February 2016.⁴ Put differently, the CPTPP was negotiated because the original text of the TPP could not come into effect because the requirements for doing so were not met. The entry into force of the TPP requires ratification by at least six Parties that together account for 85 per cent of the combined Gross Domestic Product (GDP) of all the TPP Parties.⁵ With the withdrawal of the United States from the agreement,⁶ the condition to bring the agreement into force could no longer be met,⁷ because the U.S. accounts for 62 per cent of the combined GDP of the 12 TPP Parties.⁸ Therefore, it was impossible for the remaining Parties, accounting for 38% of the total GDP, to move forward with the agreement.⁹

Therefore, the remaining 11 TPP Parties re-negotiated a separate agreement. Subsequent to the withdrawal of the U.S., the remaining 11 Parties met for the first time during a High-Level Dialogue on Integration Initiatives in the Asia-Pacific Region held in Viña Del Mar, Chile on 14–15 March 2017.¹⁰ By issuing a joint statement at the Dialogue, the Parties “reiterated their firm commitment to collaborate in keeping markets open.”¹¹ Thereafter, on the sidelines of the Asia-Pacific Economic Cooperation (APEC) Ministers Responsible for Trade, conducted on 21 May

³ See Peter A. Petri and Michael G. Plummer, “China should join the new Trans-Pacific Partnership,” Peterson Institute for International Economics (PIIE) Policy Brief 19-1 (2019), p. 1.

⁴ Australian Government Department of Foreign Affairs and Trade, “The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership Agreement: About the negotiations.” Available from <https://dfat.gov.au/trade/agreements/in-force/cptpp/negotiations/Pages/about-the-tpp-negotiations.aspx> (accessed 10 April 2019). The Department of Foreign Affairs and Trade has stated that the negotiation was an extension of the governments’ effort to bring the TPP into force.

⁵ See article 30.5 of the Trans-Pacific Partnership Agreement (hereafter, TPP), which was signed on 4 February 2016.

⁶ The U.S. left the TPP on 23 January 2017.

⁷ See Rodrigo P. Lazo and Sebastian G. Fiedler, “A requiem for the Trans-Pacific Partnership: Something new, something old and something borrowed?,” *Melbourne Journal of International Law* 118 (2017), p. 2. See also Peter A. Petri et al., “Going It Alone in the Asia-Pacific: Regional Trade Agreements Without the United States,” Peterson Institute for International Economic (PIIE) Working Paper (October 2017), p. 2.

⁸ See Malaysia’s Ministry of International Trade and Industry, “TPP and CPTPP,” updated 9 April 2019. Available from <https://fta.miti.gov.my/index.php/pages/view/71?mid=40> (accessed 9 April 2019).

⁹ After the U.S., which accounts for 62 per cent, Japan accounts for 17 per cent of the total TPP Member States’ GDP.

¹⁰ Singapore Ministry of Trade and Industry, “Minister of State Koh Poh Koon at High-Level Dialogue on Integration Initiatives in the Asia-Pacific Region,” MTI (16 March 2017). Available from <https://www.mti.gov.sg/MTIInsights/Pages/CPTPP.aspx> (accessed 16 October 2018). See also Rodrigo P. Lazo and Sebastian G. Fiedler, “A requiem for the Trans-Pacific Partnership: Something new, something old and something borrowed?,” *Melbourne Journal of International Law* 118 (2017), p. 3; Krisztina Binder, “From TPP to new trade arrangements in the Asia Pacific Region,” European Parliament Research Service Briefing (May 2017), p. 3.

¹¹ The TPP countries indicated this in their Joint Statement given on 15 March 2017 in Viña Del Mar, Chile. See also Binder, “From TPP to New Trade Arrangements,” p. 3.

2017 in Hanoi, Vietnam, the remaining Parties reiterated the need to sustain the agreement with or without the cooperation of the U.S.¹² Trade Ministers from the 11 nations also tasked senior officials with “work[ing] out the options to bring the TPP into force expeditiously and to reach particularly a balanced outcome that maintains the significant benefits of the TPP.”¹³ Having done so, the Ministers announced in November 2017 that they had agreed upon “the core elements” of the agreement.¹⁴

Negotiations on a separate agreement were concluded on 23 January 2018 in Tokyo, and the 11 participating nations signed the agreement on 8 March 2018 in Santiago, Chile. Following this, the Trans-Pacific Partnership Agreement was rechristened the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (hereafter, CPTPP).¹⁵ On 30 December 2018, the CPTPP also entered into force among the first six Parties (Singapore, New Zealand, Mexico, Japan, Canada and Australia) that had completed the ratification process within their domestic jurisdictions.¹⁶

In this context, although many of the TPP’s provisions were incorporated by reference into the CPTPP,¹⁷ the Parties also agreed to suspend several others.¹⁸ In light of this, article 2 of the CPTPP provides that, “upon the date of entry into force of this Agreement, *the Parties shall suspend the application of the provisions set out in the Annex to this Agreement*, until the Parties agree to end suspension of one or more of these provisions” (emphasis added).¹⁹ This Annex states that the TPP provisions that had been incorporated in several domains (such as investment, government procurement, customs administration and trade facilitation and intellectual property) were suspended. Regarding the chapter on intellectual property (IP), the Parties agreed, among other things, to suspend the provisions concerning patent term adjustment as well as some of the provisions dealing with patentable subject matters.

¹² Singapore Ministry of Trade and Industry, “Statement on the Trans-Pacific Partnership (TPP),” MTI (21 May 2017). Available from <https://www.mti.gov.sg/MTIInsights/Pages/CPTPP.aspx> (accessed 16 October 2018); Binder, “From TPP to new trade arrangements,” p. 4.

¹³ Ibid.

¹⁴ See Lazo and Fiedler, “A requiem for the Trans-Pacific Partnership,” p. 4.

¹⁵ Singapore Ministry of Trade and Industry, “Trans-Pacific Partnership Ministerial Statement,” MTI (11 November 2017). Available from <https://www.mti.gov.sg/MTIInsights/Pages/CPTPP.aspx> (accessed 16 October 2018). According to New Zealand’s Ministry of Foreign Affairs and Trade, the agreement is named as CPTPP (progressive), among other reasons, “because it goes beyond reducing costs for businesses. It includes commitments to safeguard high labor and environmental standards across the Asia-Pacific region.”

¹⁶ Government of Canada, “What is the CPTPP?” (26 February 2019). Available from <https://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptppg/index.aspx?lang=eng> (accessed 9 April 2019). The Comprehensive and Progressive Agreement for Trans-Pacific Partnership Ministerial Statement, Tokyo (19 January 2019). See also New Zealand’s Ministry of Business, Innovation and Employment, “Comprehensive and Progressive Agreement for Trans-Pacific Partnership” (16 January 2019). Available from <https://www.mbie.govt.nz/business-and-employment/business/intellectual-property/comprehensive-and-progressive-agreement-for-trans-pacific-partnership/> (accessed 8 April 2019). Vietnam was the seventh Party to ratify the agreement on 14 January 2019. See also Petri and Plummer, “China Should Join the New Trans-Pacific Partnership,” p. 1.

¹⁷ See article 1(1) of the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership Agreement (hereafter, CPTPP), which was signed on 8 March 2018 and entered into force on 30 December 2018. The provision reads “The Parties hereby agree that, under the terms of this Agreement, the provisions of the Trans-Pacific Partnership Agreement, done at Auckland on 4 February 2016 (‘the TPP’) are incorporated, by reference, into and made part of this Agreement *mutatis mutandis*, except for article 30.4 (Accession), article 30.5 (Entry into Force), article 30.6 (Withdrawal) and article 30.8 (Authentic Texts).”

¹⁸ See also New Zealand, “Trans-Pacific Partnership Agreement (CPTPP) Amendment Bill: Government Bill Explanatory Note” (2018), p. 1. In the Amendment Bill, New Zealand stated that “the CPTPP includes many of the elements that were negotiated as part of the TPP”. The Parties agreed also to suspend 22 elements that had been part of the TPP.

¹⁹ According to article 30.1, the annexes to the CPTPP constitute an integral part of the Agreement.

Specifically, article 7(f) of the annex provides that the rule on test data concerning biologics—medicines derived from protein through the application of a biotechnological process—was also suspended.²⁰

On this particular point, it can be useful to ask whether the suspended rules—specifically the rule regarding biologics’ test data—have a chance of being revived. As the CPTPP stands now, the suspended rules, including the rule concerning biologics test data, have no application under international law. Still, given that the suspended rules were not fully removed from the CPTPP,²¹ they may have application if and when the Parties end the suspension.²² This is one of several items implying that the suspended rules may be revived under two circumstances. Primarily, given the fact that the U.S. (specifically the Office of the United States Trade Representative [USTR]) had a strong hand in shaping the content of most of the suspended rules, the provisions may be revived if and when the U.S. rejoins the agreement. This situation may prove more than theoretical, since the U.S. has shown interest in rejoining the agreement (though no concrete action has been taken to this end). Still, at the Hanoi meeting in May 2017, the USTR declined the idea of rejoining the agreement.²³ President Trump stated on 13 April 2018 that the U.S. could rejoin the agreement, provided that the country was offered “a better deal than that negotiated by the Obama Administration.”²⁴

Secondly, the suspended rules could be reenergized regardless of whether the U.S. rejoins the agreement. In giving weight to this, for instance, Australia’s Department of Foreign Affairs and Trade stated that the suspended provisions “remain part of the TPP-11 Agreement, but they will have no application under international law.”²⁵ Going a step further, it indicated that the provisions could be “unsuspended” when the signatories decide to do so.²⁶ In a similar vein, article 2 of the Preamble to the CPTPP stipulates that the Parties may “agree to end suspension of one or more of these provisions.”²⁷ Given this prospect, the test data rule pertaining to biologics could also be revived.

Taking the above issues into account, the following sections will explore the main focus of this paper. While the second section discusses the TRIPS standard for test data protection, the third examines the nature of the obligations enshrined under the TPP’s rule on test data. The fourth section provides the legal basis for access to biologics, while the fifth section investigates whether and how the rule on test data (if unsuspended) would interfere with the obligations of the CPTPP party nations to gain access to biologics.

²⁰ Article 7(f) of the Annex reads “Article 18.51 (Biologics): all of this article including footnotes 58 through 60” are suspended.

²¹ Deborah Elms, “TPP11: Unpacking the Suspended Provisions,” Asian Trade Center Policy Brief No. 17–11 (November 2017), p. 1.

²² Footnote 2 to article 2 of the CPTPP also states that “For greater certainty, any agreement by the Parties to end a suspension shall only apply to a Party upon the completion of that Party’s applicable legal procedures.”

²³ Binder, “From TPP to New Trade Arrangements,” p. 4.

²⁴ See Martin Farrer and Agencies, “Trump says he would rejoin TPP if offered better terms than Obama,” *The Guardian* (13 April 2018). Available from <https://www.theguardian.com/world/2018/apr/13/trump-says-he-would-rejoin-tpp-if-offered-better-terms-than-obama> (accessed 12 April 2019).

²⁵ Australia Department of Foreign Affairs and Trade, “TPP-11 Suspension Explained,” Fact Sheet (21 February 2018).

²⁶ In a similar vein, Deborah Elms has argued that even if the U.S. does not rejoin, “these elements of the TPP may come back into the agreement as originally negotiated.” See Elms, “TPP11: Unpacking the Suspended Provisions,” p.

1.
²⁷ See article 2 of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Footnote 2 to article 2 also states that “For greater certainty, any agreement by the Parties to end a suspension shall only apply to a Party upon the completion of that Party’s applicable legal procedures.”

2. THE TRIPS AGREEMENT: UNDISCLOSED TEST OR OTHER DATA PROTECTION

The TRIPS Agreement obligates the Member States of the World Trade Organization (WTO) to provide protection to test data if the conditions required for the protection are met.²⁸ The nature and scope of legal protections to be given to test data, however, have been contested in the wake of the Uruguay Round of negotiations.²⁹ Bearing this in mind, it is useful to synopsise the underlying concept of test data before analyzing the main focus of this paper. A brief review of various pieces of national legislation, as well as the TRIPS Agreement demonstrates that developers (i.e., pharmaceutical companies) are often required to submit test data if they wish to market their pharmaceutical products.³⁰ In this context, national Health Regulatory Authorities (hereafter HRAs), such as the Drug Administration Department of Vietnam (DAV), Peru's Sanitary Authority (DIGEMID)³¹ and the Pharmaceutical and Medical Device Agency (PMDA) of Japan,³² often seek the submission of test data when developers wish to market a new pharmaceutical product.³³

Usually, developers generate such data over the course of their Research and Development (R&D) activities. These data are intended to confirm the safety, efficacy and quality of medicines, as well as the modality of their production. As an integral part of such data development, developers usually conduct pre-clinical³⁴ and clinical trials³⁵ on animals (either on a computer or in the laboratory) and human beings, respectively. During a pre-clinical study, they test potential medicines on animals to evaluate a wide range of issues, *inter alia*,

²⁸ See article 39(3) of the TRIPS Agreement, which provides the conditions required to be fulfilled in order for the WTO Members to give protection. In light of this, the Members are required to protect if they request the submission of such data. The provision also includes other conditions. As a case in point, though the provision has not clarified the meaning of the term, developers must submit "new chemical entities." See also Owais H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law* (Berlin; Heidelberg, Springer-Verlag, 2016), p. 79.

²⁹ See World Trade Organization (WTO), "Argentina – Certain Measures on the Protection of Patents and Test Data: Request for Consultations by the United States," WT/DS196/1 IP/D/22 (6 June 2000). See also Viviana Muñoz Tellez, "Dispute settlement under the TRIPS agreement: The United States–Brazil (2000) and United States–Argentina (2002) patent disputes," in *Research Handbook on the Interpretation and Enforcement of Intellectual Property Under WTO Rules*, volume II, Carlos M. Correa, ed. (Cheltenham, U.K. and Northampton, Massachusetts, Edward Elgar Publishing Limited, 2010), p. 231.

³⁰ Carlos M. Correa, "Data exclusivity for pharmaceuticals: TRIPS standards and industry's demands in free trade agreements," in *Research Handbook on The Protection of Intellectual Property under WTO Rules*, volume I, Carlos M. Correa ed. (Cheltenham, U.K. and Northampton, Massachusetts, Edward Elgar Publishing Limited, 2010), p. 716.

³¹ See article 2(a) of Peru's Supreme Decree N° 002-2009-SA. In Peru the HRA is known as "Dirección General de Medicamentos, Insumos y Drogas" (DIGEMID) or, in short, Sanitary Authority of the Ministry of Health.

³² The PMDA is part of the Ministry of Health, Labor and Welfare.

³³ In response to a request, developers often submit test data that demonstrate the safety, quality and efficacy of a certain biologic. See World Health Organization (WHO), "Briefing Note: Access to Medicines" (March 2006), p. 1, and Carlos M. Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva, South Centre, 2002), pp. 1–3.

³⁴ Bruce Rasmussen, *Innovation and Commercialisation in the Biopharmaceutical Industry: Creating and Capturing Value* (Cheltenham, U.K., and Northampton, Massachusetts, Edward Elgar, 2010), p. 77. The pre-clinical trial is one that follows the discovery phase.

³⁵ According to the WHO Commission on Intellectual Property, Innovation and Public Health Report, clinical trials are defined as "any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of an investigational product or to identify any adverse reactions to an investigational product or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety or efficacy. The terms clinical trial and clinical study are synonymous." See WHO Commission on Intellectual Property Rights, Innovation and Public Health, *Report: Public health, innovation and intellectual property rights* (Geneva, 2006), p. 192.

regardless of whether the medicine is non-toxic (safe).³⁶ Having verified the outcome of the pre-clinical trial, developers often file an Investigational New Drug³⁷ (IND) application with HRAs to get authorization to study the potential medicine on humans.³⁸ If a particular HRA endorses the application, developers proceed to a clinical trial, meaning that the pre-clinical phase lays the foundation for a subsequent study (clinical trial) on human beings.³⁹

A clinical trial involves several stages (usually four)⁴⁰ that help examine the safety and effectiveness of a new medicine on humans. During the first phase, the medicine is administered to humans (usually on healthy volunteers⁴¹) to evaluate its safety and collect “information on toxicity of the dosage and metabolic effects.”⁴² Similarly, phase two is conducted on humans who live with the targeted disease or condition.⁴³ In this phase, by conducting a study on “targeted” patients, developers aim to ascertain the effectiveness of a candidate medicine, its frequency of administration and many other related issues.⁴⁴ Essentially, the second phase, among other things, aims to obtain evidence of the medicine’s safety and preliminary data on its efficacy.⁴⁵ Compared to the first phase, which involves a smaller number (usually 20–100) of healthy volunteers, the second phase tests a medicine on a relatively large number of patients⁴⁶ to monitor its efficacy and short-term side effects. The third stage of a clinical trial, which is generally the pre-marketing step, will be conducted on a greater number of human beings (i.e., patients) to confirm its efficacy and control any adverse reactions to it.⁴⁷

Finally, if developers believe the test results confirm the safety and efficacy of the medicine, they assemble the outcome of their trials (preclinical, clinical, formulations and so on) and file an application with a particular HRA, such as the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) or the Instituto de Salud Pública (ISP) of Chile,⁴⁸ to obtain marketing authorization.⁴⁹ Thus, the data (proof of the safety, efficacy and quality of a medicine)

³⁶ Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*, p. 2.

³⁷ Investigational New Drug (IND) is a request filed with HRA to get authorization to administer forthcoming medicines to humans. See Sam F. Halabi, “The drug repurposing ecosystem: Intellectual property incentives, market exclusivity, and the future of ‘new’ medicines,” *The Yale Journal of Law & Technology*, 20 (2018), p. 16. See also Sandeep Sinha and Divya Vohora, “Drug discovery and development: An overview,” in *Pharmaceutical Medicine and Translational Clinical Research*, Divya Vohora and Gursharan Singh, eds. (London and San Diego, Academic Press, 2018), p. 27.

³⁸ See Sinha and Vohora, “Drug discovery and development: An overview,” p. 27; Rasmussen, *Innovation and Commercialisation in the Biopharmaceutical Industry*, p. 77.

³⁹ Carlos M. Correa, “Protecting test data for pharmaceutical and agrochemical products under free trade agreements,” in *Negotiating Health: Intellectual Property and Access to Medicines*, Pedro Roffe et al., eds. (London, Earthscan, 2006), p. 81. See also U.S. Food and Drug Administration, “Step 2: Pre-clinical research” (FDA, updated 4 January 2018). Available from <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm> (accessed 16 January 2018).

⁴⁰ See Halabi, “The drug repurposing ecosystem: Intellectual property incentives, market exclusivity, and the future of ‘new’ medicines,” p. 16. See also Meir Perez Pugatch, “Intellectual property, data exclusivity, innovation and market access,” in *Negotiating Health: Intellectual Property and Access to Medicines*, Pedro Roffe et al., eds. (London, Earthscan, 2006), p. 97.

⁴¹ Sinha and Vohora, “Drug Discovery and Development: An Overview,” p. 28.

⁴² Henry G. Grabowski et al., “The price of innovation: New estimates of drug development costs,” *Journal of Health Economics* 22 (2003), pp. 155–156. See also Correa, “Protecting test data for pharmaceutical and agrochemical products,” p. 81.

⁴³ Grabowski et al., “The price of innovation: new estimates of drug development costs,” p. 156.

⁴⁴ Sinha and Vohora, “Drug discovery and development: An overview,” p. 28.

⁴⁵ Grabowski et al., “The price of innovation: new estimates of drug development costs,” p. 156. See also Halabi, “The drug repurposing ecosystem,” pp. 15–18.

⁴⁶ U.S. Food and Drug Administration, “Step 3: Clinical research,” FDA, updated 4 January 2018. Available from <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm> (accessed 16 January 2018).

⁴⁷ *Ibid.*

⁴⁸ See article 89 of Chile’s Industrial Property Law No. 19.039.

⁴⁹ Halabi, “The drug repurposing ecosystem,” pp. 15–18.

they generate over the course of R&D of a medicine are generally referred to as test data.⁵⁰ If the HRA approves the data, developers will have the right to market this medicine as a reference (pioneer, originator or branded) medicine.

As stated earlier, generators (developers) are often required to submit their data. Along with the test data, an HRA also requires the submission of “other data,” which, among other things, demonstrate the medicine’s composition and modality of production, along with storage requirements and many other details.⁵¹ Beyond the data submitted for the purpose of obtaining marketing approval, generators are often required to submit “any planned phase four study,” which will generally be conducted after securing marketing rights.⁵² The post-marketing safety assessment (the fourth stage of a clinical trial) is often planned to identify any previously unseen side effects of a medicine already marketed.⁵³ During this stage, several thousand volunteers with the targeted disease or condition will be subject to a study, with a view to establishing that the medicine works as expected.⁵⁴ Essentially, the fourth stage is intended to identify, among other issues, any long-term undesirable effects of a medicine.

It is useful to examine the scope of legal protection given to such data under the TRIPS Agreement. As stated, regardless of the introduction of test data protection in article 39(3) of TRIPS, the scope of legal protection given to such data has remained a point of controversy.⁵⁵ While some developed countries (especially countries that have R&D capacity), guided primarily by the U.S., have construed the provision as implying test data exclusivity,⁵⁶ other countries have approached the nature of legal obligation embedded in article 39(3) as merely requiring test data protection, not exclusivity.⁵⁷ With these issues in mind, it is important to discuss at this point whether the rule on test data, as enshrined in article 39(3) of the TRIPS Agreement, is in fact tantamount to test data exclusivity. Under the heading of “Protection of Undisclosed Information,” article 39(3) provides that:

⁵⁰ Antonia Gustavo Trombetta, “Negotiating for Argentina,” in *The Making of the TRIPS Agreement: Personal Insights from Uruguay Round Negotiation*, Jayashree Watal and Antony Taubman, eds. (Geneva, World Trade Organization, 2015), p. 269.

⁵¹ Along with the test data, governments often require the submission of other data that demonstrate, among other things, how a medicine will be manufactured. See also Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*, p. 73.

⁵² Halabi, “The drug repurposing ecosystem,” pp. 15–18.

⁵³ Pugatch, “Intellectual property, data exclusivity, innovation and market access,” p. 97. See also the United Nations Secretary-General’s High-Level Panel on Access to Medicines (hereafter, UNHLP), “Promoting Innovation and Access to Health Technologies,” UNHLP Report (September 2016), p. 5. See also Rasmussen, *Innovation and Commercialisation in the Biopharmaceutical Industry*, p. 78.

⁵⁴ Halabi, “The drug repurposing ecosystem,” p. 16; U.S. Food and Drug Administration, “Step 3: Clinical research.”

⁵⁵ In particular, given the lack of consensus on the normative content, article 39(3) has been subject to differing interpretations across developing as well as developed nations. See for instance International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), “Data exclusivity: Encouraging development of new medicines,” IFPMA (June 2011), pp. 5–6. The Federation argued that article 39(3) of the TRIPS Agreement provides test data exclusivity rather than test data protection. It argues that the phrase “unfair commercial use” is meant to indicate test data exclusivity. See also Charles Clift, “Data protection and data exclusivity in pharmaceuticals and agrochemicals,” in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, A. Krattiger et al., eds. (2007), pp. 431–435.

⁵⁶ Aaron Xavier Fellmeth, “Secrecy, monopoly, and access to pharmaceuticals in international trade law: Protection of marketing approval data Under the TRIPS Agreement,” *Harvard International Law Journal*, vol. 45, No. 2 (2004), p. 445. See also Muñoz Tellez, “The United States–Brazil (2000) and United States–Argentina (2002) patent disputes,” in *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules*, Carlos M. Correa, ed. (Cheltenham, U.K. and Northampton, Massachusetts, Edward Elgar Publishing, 2010), p. 23.

⁵⁷ Fellmeth, “Secrecy, Monopoly, and Access to Pharmaceuticals,” p. 448.

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.

The paragraph imposes two major obligations on WTO Members. Firstly, Members are bound to protect the test data against “unfair commercial use.”⁵⁸ The provision, however, does not define the constituent elements of unfair commercial use.⁵⁹ Secondly, article 39(3) requires countries to protect test 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.”⁶⁰

The provision of such protection, however, is contingent upon the condition that the data submitted must relate to a “new chemical entity.”⁶¹ Although the agreement fails to clarify the meaning of the word “new,”⁶² the requirement that a marketing application be made in relation to “new” chemical entity may refer to the absence of any prior marketing application for the same medicine.⁶³ If an application for marketing has already been filed with an HRA for a particular medicine, any subsequent marketing application to be filed for the same medicine may not be new.⁶⁴ Provided that the conditions set under the provision are met, a recipient State is bound to protect the manufacturer against unfair commercial use and unsubstantiated disclosure.⁶⁵ As noted, some developed nations have interpreted the provision as meaning test data exclusivity (rather than test data protection).⁶⁶ Despite this claim, a close examination of article 39(3) of

⁵⁸ There is definitive answer to the question of what constitutes unfair commercial competition. It may refer to “acts contrary to business practices.” For this see World Trade Organization (WTO), *The Making of the TRIPS Agreement: Personal insights from the Uruguay Round Negotiation*, p. 269. Under this term, Member states to the TRIPS have a wider margin of appreciation to delineate the constituent elements of unfair commercial use. See also Correa, “Protecting test data for pharmaceutical and agrochemical products,” p. 85.

⁵⁹ The International Bureau of the World Intellectual Property Organization (WIPO) provides some of the commercial uses that are tantamount to unfair commercial use. World Intellectual Property Organization (WIPO), “Model provisions on protection against unfair competition: Articles and Notes” (1996), pp. 47–60. Similarly, in a consultation initiated by the U.S. before the Dispute Settlement Body (DSB) against Argentina’s law, Argentina argued that the practice of receiving an application from a developer of generics is not tantamount to unfair commercial use. On the other hand, the U.S. argued that any use of a reference medicine’s data without the consent of a reference producer constitutes unfair commercial use. See World Trade Organization, “Argentina—Certain Measures on the Protection of Patents and Test Data: Request for Consultation by the United States,” WT/DS196/1 IP/D/22 (6 June 2000). See also Muñoz Tellez, “The United States–Brazil (2000) and United States–Argentina (2002) patent disputes,” p. 231.

⁶⁰ See article 39(3) of TRIPS.

⁶¹ *Ibid.*

⁶² In the Brussels Draft of the TRIPS Agreement, the phrase a “new pharmaceutical product” was used, although in the final draft the phrase “new chemical entity” has been integrated.

⁶³ See Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, (London, Sweet and Maxwell, 2008), p. 427. See also Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*, p. 74.

⁶⁴ This means that the Member States of WTO are required to give protection to data submitted with regard to “new chemical entities” (not new forms of administering existing medicines). See Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals*, p. 75.

⁶⁵ See article 39(3) the TRIPS Agreement.

⁶⁶ While test data exclusivity blocks reliance by third Parties on the test data to be submitted for the purpose of a reference biologic, on the other hand, test data protection consists of fair exceptions that facilitate reliance by third parties on pre-clinical and clinical data. See also Karin Timmermans, “Monopolizing clinical trial data: Implications and trends,” *PLoS Medicine*, vol. 4, No. 2 (February 2007), pp. 0206–0207. Doi:10.1371/journal.pmed.0040002.

TRIPS does not seem to reveal a guarantee of test data exclusivity.⁶⁷ A number of justifications can be given for this assertion.

First, when the protection given in article 39(3) is compared with test data exclusivity, which tends to prevent HRAs from relying on test data, the TRIPS provision allows reliance on such data, provided that some of its conditions are satisfied.⁶⁸ This is because, regardless of the obligations imposed, WTO Members have the right to limit their protection under two circumstances. According to the provision, a member is free to disclose the data if the disclosure is “necessary” to protect the public.⁶⁹ Within the context of the provision, a Member may disclose test data on the condition that its disclosure is not tantamount to “unfair commercial use.”⁷⁰ If a Member takes steps “to ensure that the data are protected against unfair commercial use,” the member is not bound to conceal the data. As a consequence, a Party’s HRA⁷¹ has the right to receive and process an application from a third party (such as a biosimilar producer) that relies on the test data for the purpose of a reference biologic.⁷² According to this argument, it a member has discretion to determine the underlying justification for the requirement to disclose test data.⁷³

Other factors also support the assertion that test data exclusivity lies beyond the scope of article 39(3). The argument, in this regard, could develop from a cumulative reading of articles 39(1) and 39(3) of TRIPS. Article 39(1) sets out that

in the course of ensuring effective protection against unfair competition as provided in article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.⁷⁴

⁶⁷ See Ellen F. M. ‘t Hoen et al., “Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation,” *Journal of Pharmaceutical Policy and Practice* (2017), p. 2. Doi 10.1186/s40545-017-0107-9.

⁶⁸ See also, the case *Bayer Inc. v. the Attorney General of Canada and the Ministry of Health*. Federal Court of Appeal of Canada, “Federal Court of Appeal Decision: Bayer Inc. versus Canada (Attorney General),” File Numbers A-679-98 (19 May 1999).

⁶⁹ Under such a circumstance, a State has the right to disclose the content of such data, provided that the disclosure is “necessary” to protect the public. See Fellmeth, “Secrecy, monopoly, and access to pharmaceuticals,” pp. 450–451.

⁷⁰ Even though the provision does not specify the meaning of “unfair commercial use,” some scholars argue that use by “a competitor could be unfair if they give to a competitor a springboard to shortcut R&D efforts.” A State, however, may not engage in unfair competition, as its purpose is to implement its legitimate objective (i.e., ensure access to medicines). See Gervais, *The TRIPS Agreement Drafting History and Analysis*, p. 428.

⁷¹ See the Federal Committee for Protection from Sanitary Risks (COFEPRIS) in Mexico and ISP in Chile.

⁷² Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards*, pp. 13–14. See also Clift, “Data protection and data exclusivity in pharmaceuticals and agrochemicals,” p. 432, and Shaikh, *Access to Medicine Versus Test Data Exclusivity*, pp. 45 and 224.

⁷³ See the Report of the General Agreement on Tariffs and Trade (GATT) Panel on the case United States - Restrictions on Imports of Tuna (DS29/R) (16 June 1994), paras. 5.30–5.39. The panel’s report demonstrates that it is up to the contracting nation to prove the necessity requirement. This means that, as long as the nations are able to bear the burden of proof to show the necessity of the measures they take, they are in a position to disclose test data.

⁷⁴ In light of this, one could infer that in interpreting the scope of legal protection embedded in article 39(3), recourse should be made to article 39(1) of the agreement, which makes an explicit reference to article 10bis of the Paris Convention for the Protection of Industrial Property. This means that the scope of “unfair commercial use,” as vested in article 39(3) of TRIPS, must be read in light of unfair commercial use, as stipulated in article 10bis of the Paris Convention. The reference in article 39(1) to article 10bis of the Paris Convention may imply that the obligation embedded in article 39(3) should be carried out in light of the constituent elements enshrined in article 10bis of the Paris Convention.

The phrase “in the course of ensuring effective protection against unfair competition as provided in article 10*bis* of the Paris Convention (1967)” may suggest that the protection to be given to test data in article 39(3) should be interpreted in light of article 10*bis* of the Paris Convention for the Protection of Industrial Property.⁷⁵ In this context, the Paris Convention is meant to serve as an interpretative guide to the obligations enshrined in article 39(3). Given this condition, the logical deduction to be made from the reference to article 10*bis* is that the TRIPS provision must give protection to test data in a manner sought under article 10*bis* of the Paris Convention.⁷⁶ As a result, this may imply that, given that article 10*bis* does not embrace test data exclusivity, the TRIPS provision seems to lack test data exclusivity.

Beyond the preceding issues, another line of argument could be based on the negotiation history of article 39(3). Despite an attempt by some developed nations to integrate test data exclusivity during the Uruguay Rounds of negotiations, certain elements of test data exclusivity that had been incorporated in earlier drafts were explicitly removed from the final text. For example, the Brussels Draft⁷⁷ of December 1990 reveals that some features that had been intended to provide test data exclusivity were removed from the scope of Annex 1C of the Marrakesh Agreement. In particular, article 42(4A) of the Brussels Draft sets out that

PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.].⁷⁸

The phrase “unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time period, generally no less than five years” is one characteristic of test data exclusivity and had been in 1994 explicitly barred from the scope of the final text. As Carlos Correa and Daniel Gervais correctly state, in this context, regardless of the endeavor to incorporate stronger protections for test data in article 39(3),⁷⁹ the proposal to do so was eventually dropped by the negotiating countries. The rejection of such constituent elements from the final draft indicates that, from the very outset, the negotiating countries envisioned the inclusion of test data protection, not test data exclusivity. It might therefore be inferred that, had the provision been in a position to adopt test data exclusivity, it would not have removed from the final version some elements related to test data exclusivity that had been proposed under the Brussels Draft of 1990.

⁷⁵ This is another way of saying that the obligation in article 10*bis* has now become an integral part of the TRIPS provision.

⁷⁶ As a case in point, Argentina, during its consultation with the U.S., argued over the scope of article 39(3). See also Muñoz Tellez, “The United States–Brazil (2000) and United States–Argentina (2002) patent disputes,” p. 231.

⁷⁷ Uruguay Round–Trade Negotiations Committee, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations–Revision, Document MTN.TNC/W/35/Rev.1 (3 December 1990).

⁷⁸ *Ibid.*; Gervais, *The TRIPS Agreement Drafting History and Analysis*, pp. 420–429.

⁷⁹ Correa, “Protecting test data for pharmaceutical and agrochemical products,” p. 85. See also Gervais, *The TRIPS Agreement Drafting History and Analysis*, pp. 420–428.

Therefore, it is evident that article 39(3) simply protects pre-clinical and clinical data against unfair commercial use and “unauthorized” disclosure.⁸⁰ Bearing in mind the issues discussed, the next section will inquire into the nature of legal obligation embodied in the TPP’s Intellectual Property Rights (IPRs) chapter.

⁸⁰ In a nutshell, the provision seeks to prohibit merely any act of competition contrary to honest commercial practices. See Jerome H. Reichman, “The international legal status of undisclosed clinical trial data: From private to public goods?,” in *Negotiating Health: Intellectual Property and Access to Medicines*, Pedro Roffe et al., eds. (London, Earthscan, 2006), p. 133ff.

3. THE TPP'S IP RULE ON TEST DATA CONCERNING BIOLOGICS

The WTO Members, which in this context are also the CPTPP Parties, are required in section 2 of the TPP to provide protection to the test data to be submitted for marketing approval of small-molecule medicines, as well as biologics.⁸¹ With this in mind, it is essential to examine the rule on test data relating to protein-based biologics and determine whether and how the rule interferes with the realization of access to biologics. Within this context, the IP chapter lays out the rule that addresses biologics in article 18.51. More specifically, article 18.51(2) defines a biologic as “a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.”⁸²

Examining the definitional elements integrated into the provision sheds light on the scope of application of the rule on test data relating to biologics. Seen from this angle, the provision's scope of application could be twofold. First, the rule can be applied if the test data to be submitted are fully developed from proteins through the application of a biotechnological process.⁸³ In this regard, though the provision has not defined “biotechnology,” it includes, among other technologies, the use of the Recombinant Deoxyribonucleic Acid (rDNA) technique,⁸⁴ which relates to the transfer of “genetic material from one organism to another.”⁸⁵ Secondly, the scope of application of article 18.51 can also indicate the situation that the test data to be submitted “contain” (i.e., use) proteins produced through a biotechnological process. Though the provision does not clarify the percentage of protein content required, it tacitly suggests that a particular biologic may either entirely comprise proteins or contain (use) some elements in it. This can be inferred from the wording of article 18.51(2). While the phrase “a product that is” suggests that a biologic should be derived fully from protein, the phrase “alternatively contains” may, on the other hand, indicate that the rule on test data applies to biologics that consist of a certain percentage of protein.⁸⁶

⁸¹ See article 18.50(1)(a)(ii) of the TPP's IPRs chapter.

⁸² *Ibid.*, article 18.51(2).

⁸³ The report of the United Nations Secretary-General's High-Level Panel on Access to Medicines defines biotechnology as “the use of biological processes, organisms, or systems to manufacture treatments intended to improve the quality of human life. Biotechnology is an interdisciplinary science-based technology that combines knowledge from different fields, such as microbiology, biochemistry, genetics, process technology and chemical engineering.” See United Nations Secretary-General's High-Level Panel on Access to Medicines, “Promoting Innovation and Access to Health Technologies,” UNHLP Report (September 2016), p. 5. A report of the United Nations Secretary-General also defines biotechnology as “a collection of techniques or processes that employ organisms or their units to develop useful products and services, has the potential to become a powerful tool in meeting the challenges posed by food insecurity, industrial underdevelopment, environmental degradation and disease”. See United Nations Secretary-General, “Macroeconomic policy questions: Science and technology for development: Impact of new biotechnologies, with particular attention to sustainable development, including food security, health and economic productivity,” A/58/76 (9 May 2003), para. 6.

⁸⁴ See Thomas Cottier, “Genetic engineering, trade and human rights,” in *Genetic Engineering and the World Trade System: World Trade Forum*, Thomas Cottier and Daniel Wüger, eds. (New York, Cambridge University Press, 2008).

⁸⁵ See Organization for Economic Co-Operation and Development (OECD), “Statistical definition of biotechnology” (2005). Available from <http://www.oecd.org/sti/biotech/statisticaldefinitionofbiotechnology.htm> (accessed 17 January 2018). It defines biotechnology as “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.”

⁸⁶ See article 18.51 (2) of the TPP's IPRs chapter. This means that the provision may apply also to cases like antiviral (AIDS medicines), which is a mix of biologics and chemical synthesis, provided that it is produced through a biotechnology process. See Mark Trusheim et al., “Characterizing markets for biopharmaceutical innovations: Do biologics differ from small molecules?,” National Bureau of Economic Research, Working Paper Series 16014 (2010), p. 16.

Bearing in mind the scope of application of the provision, paragraph one of the provision (article 18.51(1)(a)) stipulates that “a Party shall provide effective market protection through the implementation of test data protection *for a period of at least eight years*” (emphasis added).⁸⁷ Specifically, article 18.51(1)(a) makes reference to article 18.50 (the test data rule on small-molecule medicine). This means that, as with small-molecule medicine, the implementation by TPP Parties of the obligations embedded in the provision is contingent upon the satisfaction of certain preconditions. The first condition, which is somewhat similar to article 39(3) of the TRIPS and article 18.50(1) of the TPP, provides that, if a Party to the TPP requests the submission of test data, it is bound to implement the obligation included under the provision.⁸⁸ Similarly, the second condition requires generators to submit test data to market a new pharmaceutical product (here, a reference biologic). In light of this, article 18.51(1)(a) states that a signatory gives such protection to “a new pharmaceutical product that is or contains a biologic.”⁸⁹ Going further, the provision stipulates other conditions that must be satisfied for the TPP Parties to implement the obligations embedded in the provision. Therefore, if the conditions (such as a new pharmaceutical product and a Party’s request for data) are met, a requesting Party is bound to provide effective market protection to the data submitted in order to market a new pharmaceutical product.⁹⁰

According to article 18.51(1), effective market protection shall be given through the adoption of test data exclusivity (not test data protection). In this regard, the provision provides two alternatives, although ultimately similar, tracks for implementing test data exclusivity concerning biologics. Put differently, in order to fully implement test data exclusivity on biologics, the signatories are required to comply with one of the two modes (henceforth, Option A or B) enshrined in article 18.51. The first mode, Option A, is embedded in article 18.51(1)(a) and specifies that a Party

with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, shall provide effective market protection through the implementation of protection of *test data for a period of at least eight years*⁹¹ from the date of first marketing approval of that product in that Party” (emphasis added).

⁸⁷ The provision specifically reads “a Party shall with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of article 18.50.1 (Protection of Undisclosed Test or Other Data) and article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party.”

⁸⁸ In particular, the cumulative reading of article 18.51(1) and footnote 51 to article 18.50 show that test data exclusivity should be given to developers if the TPP country seeks the submission of test data. Similarly, footnote 51 to article 18.50(1)(a) provides that the obligation enshrined in article 18.51 applies if the Parties require the submission of the test data.

⁸⁹ See article 18.51. In this regard, although the phrase fails to specifically define the term “new pharmaceutical product” with regard to biologics, a reference to articles 18.50 and 18.52 suggest that a new pharmaceutical product could refer to a biologic that has never been approved in a particular Signatory State to the TPP. See also Pugatch, “Intellectual property, data exclusivity, innovation and market access,” p. 101. “New pharmaceutical product” may also mean a particular biologic that has never been approved across any HRAs.

⁹⁰ See article 18.51(1) of the TPP’s IPRs chapter.

⁹¹ In this context, even if it is argued that test data exclusivity is needed to ensure the continuity of innovation, the period incorporated could be longer when compared to the available evidence. In principle, there is no a concrete standard proving that a certain period of exclusivity is necessary to ensure innovation in biologics sectors. Despite this general trend, a number of stakeholders have attempted to show a timeframe required to boost innovation. The U.S. Congressional Budget (CBO) argued that the length of data exclusivity needed to help companies recoup their costs relating to the production of clinical trials and development of new medicines does not surpass a maximum of seven years. This evidence was considered during the negotiation of article 18.51. Therefore, the inclusion of eight

Pursuant to the provision (article 18.51(1)(a)), test data exclusivity shall be given for the purpose of providing “effective market protection.” In this context, the phrase “Party shall provide effective market protection through the implementation,” as embedded in Option A,⁹² suggests that a Party is bound to deliver effective market protection through the adoption of test data exclusivity. Under this Option, the Parties must provide test data exclusivity for a minimum of eight years.⁹³ They are required to deliver such exclusivity from the date they give marketing authorization to developers of the data.⁹⁴

An alternative mode (Option B) is also provided in article 18.51(1)(b)(i–iii). According to Option B, a Party shall provide effective market protection by implementing test data exclusivity for at least five years.⁹⁵ Although in principle Option B requires test data exclusivity for five years, the provision (18.51(1)(b)(i)) requires accompanying legal commitments from the Parties. Seen in this light, a Party that wants to adopt Option B is also bound to provide “other measures,”⁹⁶ a phrase that the provision does not define precisely, but to which some national institutions⁹⁷ of the Parties have attempted to give meaning. For example, Australia’s Department of Foreign Affairs and Trade has argued that the phrase refers, among other things, to measures like “regulatory settings, patents, and the time it takes for follow-on medicines to become established in the market.”⁹⁸ In stark contrast to this, the Intellectual Property Rights–Trade Advisory Committee (ITAC-15) on the Trans-Pacific Partnership Agreement argued in a report submitted to the USTR that the measures referred to “government-applied measures, rather than point[ing] to the effect of patents or natural market forces.”⁹⁹

Beyond even these “other measures,” a Party that chooses Option B is required to implement an additional legal commitment.¹⁰⁰ Article 18.51(1)(b)(iii) states that a Party shall provide effective market protection by “recognizing that market circumstances also contribute to effective market protection.”¹⁰¹ It can be inferred from this provision that, beyond the

years or the pressure exerted during the negotiation to secure a longer period (twelve years) may reflect a desire to collect returns excessively, rather than to balance the needs of access to medicines and innovation.

⁹² See article 18.51(1) of the TPP’s IPRs chapter.

⁹³ *Ibid.*, article 18.51(1)(a).

⁹⁴ Nonetheless, see part two of Annex 18-D, which provides specific obligations with regard to Peru. The annex exceptionally entitles Peru to count the period of data exclusivity from the date of the first marketing authorization abroad rather than from later marketing approval in Peru. Similarly, Annex 18-C provides a specific time with respect to Malaysia; it reads “Malaysia may, for the purpose of granting protection as specified in article 18.51.1 (Biologics), require an applicant to commence the process of obtaining marketing approval for pharmaceutical products covered under those articles within 18 months from the date that the product is first granted marketing approval in any country.” See also Raquel Artecona & Rosine M. Plank-Brumback, “Access to medicines and incentives for innovation: The balance struck in the Trans-Pacific Partnership (TPP) on intellectual property (patent and data exclusivity) protection for pharmaceutical products,” ECLAC, *Studies and Perspectives Series 16* (2016), p. 30.

⁹⁵ Article 18.51(1)(b)(i–iii) specifically reads that a Party shall “with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection: (i) through the implementation of article 18.50.1 (Protection of Undisclosed Test or Other Data) and article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party, (ii) through other measures, and (iii) recognizing that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.”

⁹⁶ See article 18.51(1)(b)(ii) of the TPP’s IPRs chapter.

⁹⁷ See Australia’s Department of Foreign Affairs and Trade, “Trans-Pacific Partnership Outcomes: Biologics,” *Fact Sheet* (7 July 2016), p. 2.

⁹⁸ *Ibid.*

⁹⁹ See a report by the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), *Advisory Committee Report to the President, the Congress and the U.S. Trade Representative on the Trans-Pacific Partnership Trade Agreement* (3 December 2015), p. 17.

¹⁰⁰ See article 18.51.1(b)(iii) of the TPP’s IPRs chapter.

¹⁰¹ *Ibid.*

requirements (“five years” and “other measures”) of article 18.51(1)(b)(i and ii), the Parties are also bound to take into account market circumstances to ensure the market effectively protects generators.¹⁰²

The nature of the obligations imposed by Option B is relatively imprecise due to the inclusion of nebulous phrases like “other measures” and “recognition of market circumstances.” As a result, some Parties have tried to interpret Option B as not imposing any obligations beyond five years of test data exclusivity.¹⁰³ Although this interpretation is relatively preferable from the viewpoint of the right to biologics, the provision does not seem to require test data exclusivity for only five years. A number of arguments could be raised to rebut the interpretation that Option B does not require more than five years of exclusivity.

Firstly, the duration of five years, as seen above, must be supported by two kinds of commitments (other measures and market recognition). A cumulative reading of the principle (five years of test data exclusivity), in tandem with the additional legal commitments, demonstrates that, by implementing the obligations enshrined under Option B (article 18.51(1)(b)), the Parties must “deliver a comparable outcome in the market.”¹⁰⁴ In particular, article 18.51(1)(b)(iii) states that a Party that implements Option B must “recognize that the market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.” Regardless of the lack of a clear definition of “a comparable outcome,” it may imply that, irrespective of the Parties’ choice (Option A or B), both options are intended to result ultimately in comparable or relatively similar exclusivity.¹⁰⁵

The second line of argument may flow from the *a contrario* reading of the provision. If one argues that the duration of Option B is shorter than that of Option A, the *a contrario* reading of this interpretation may mean that a producer of a cost-cutting biologic (biosimilar) has the right to rely on test data as soon as the five-year period of test data exclusivity expires. This may, however, prove a difficult argument to make, since allowing competitors does not result in the effective and comparable outcome required under Option A. As a consequence, it can be inferred that Option B might not be designed to provide a shorter period of exclusivity. In giving weight to this assertion, Ambassador Michael Forman (United States Trade Representative

¹⁰² Even though both of these phrases (“other measures,” as well as recognition of the market) are vague and have not been properly clarified, the provision requires five years of test data exclusivity and other measures, as well as the recognition of market circumstances.

¹⁰³ See Australian Government Department of Foreign Affairs and Trade, “*Trans-Pacific Partnership Agreement Outcomes: Biologics*,” Fact sheet (7 July 2016), pp. 1–2. Available from <http://dfat.gov.au/trade/agreements/tpp/outcomes-documents/Pages/outcomes-biologics.aspx> (accessed 17 October 2017). See also Duncan Matthews and Herbert Zerch, eds., *Research Handbook on Intellectual Property and the Life Sciences* (Cheltenham, U.K. and Northampton, Massachusetts, Edward Elgar Publishing, 2017), pp. 113–117; Sanya S. Reid, “Ambiguity leads to fallacy: Biologics exclusivity in the Trans-Pacific Partnership,” *Third World Network and Public Citizen* (2015), p. 2; Jane Kelsey, “New Zealand and the Trans-Pacific Partnership Agreement Negotiations: Strategy, content and lessons,” in *New Zealand and the World: Past, Present and Future*, Robert G. Patman et al., eds. (Singapore, World Scientific Publishing Co., 2018), pp. 150–153; Inside U.S. Trade, “Hatch-Obama call fails to yield biologics deal; Lame duck hopes still alive,” vol. 34, No. 24 (16 June 2016), available from: <https://insidetrade.com/inside-us-trade/hatch-obama-call-fails-yield-biologics-deal-lame-duck-hopes-still-alive>, (accessed 18 October 2017). Some of the Parties (specifically Australia, Chile and New Zealand) have argued from the very outset that Option B does not impose an obligation that exceeds five years.

¹⁰⁴ See article 18.51.1(b)(iii) of the TPP’s IPRs chapter.

¹⁰⁵ For a similar conclusion see Frederick M. Abbot, “The evolution of public health provisions in preferential trade and investment agreements of the United States,” in *Current Alliances in International Intellectual Property Lawmaking: The Emergence and Impact of Mega-Regionals*, Xavier Seuba and Pedro Roffe, eds. (Geneva and Strasbourg, CEIPI-ICTSD, 2017), p. 55.

during the negotiations) has also argued that the provision gives eight “real” years of data exclusivity as a solution to the biologics issue.¹⁰⁶

Having examined the nature of obligations enshrined in article 18.51, the next section examines whether and how the obligations of article 18.51 are at odds with the right to biologics. It is necessary, however, to discuss the legal foundation of access to biologics before proceeding to analyze *whether* and *how* the provision on test data interferes with the right to biologics.

¹⁰⁶ Ambassador Michael Forman was the USTR representative during the TPP negotiation. See Inside U.S. Trade, “Hatch-Obama call fails to yield biologics deal; Lame duck hopes still alive.” U.S. officials have argued that other measures, which are required under Option B, will have the effect of extending the exclusivity period to eight years total.

4. ACCESS TO BIOLOGICS UNDER INTERNATIONAL HUMAN RIGHTS INSTRUMENTS

The contemporary understanding of human rights was introduced into international law with the adoption of the Charter of the United Nations (hereafter, U.N. Charter).¹⁰⁷ Since then, human-rights instruments addressing various subjects have also been adopted at international fora. Examples include the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). One of several human rights included in the ICESCR is the right to health.¹⁰⁸ This right, however, was also enumerated under the Constitution of the World Health Organization (WHO) even before the adoption of the ICESCR. The Preamble to the WHO Constitution provides that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”

Within this context, although a number of other instruments, including the Convention on the Rights of the Child, are also relevant with respect to the right to health, the leading international human-rights instrument that provides the right to health is the ICESCR.¹⁰⁹ The most relevant provision in this regard is article 12, which requires the State Parties to the ICESCR to respect, fulfil and protect the rights and obligations included under the provision. Article 12(1) provides that the State Parties to the ICESCR “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” An in-depth reading of the provision shows that, while the first paragraph provides the general right to health, some of the steps to be taken by State Parties to the ICESCR are also enumerated in paragraph two of the Covenant.¹¹⁰

So that the State Parties can implement their obligations pertaining to such rights, paragraph two of the provision provides four concrete steps.¹¹¹ Since these steps are purely illustrative, however, the full realization of the right to health might also be subject to other relevant steps.¹¹² Accordingly, article 12(2)(a) provides that steps shall be taken that are necessary for “the provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child.” By emphasizing the full realization of the right, the provision further requires that the steps taken also be necessary for “the improvement of all aspects of environmental and industrial hygiene.” Furthermore, article 12(2)(c) provides that the measures taken by the State Parties must be aimed at preventing, treating and controlling epidemic, endemic, occupational and other diseases.¹¹³ In a similar vein, article 12(2)(d) provides that the

¹⁰⁷ Théodore H MacDonald, *The Global Human Right to Health: Dream or Possibility?* (Boca Raton, Florida, CRC Press, 2007), p. 1.

¹⁰⁸ Brigit Toebes, “Towards an improved understanding of the international human right to health,” *Human Rights Quarterly*, vol. 21, No. 3 (1999), pp. 663–664.

¹⁰⁹ See the Committee on ESCR, General Comment No. 14, (2000), para. 2. See also Toebes, “Towards an improved understanding of the international human right to health,” p. 663.

¹¹⁰ See Stephen P. Marks, “The emergence and scope of the human right to health,” in *Advancing the Human Rights to Health*, Lawrence O. Gostin et al., eds. (Oxford, Oxford University Press, 2013), p. 7. See also, Thérèse Murphy, *Health and Human Rights*, (Oxford and Portland, OR, Hart Publishing, 2013), p. 43.

¹¹¹ See article 12 (2) of the ICESCR.

¹¹² See the Committee on ESCR, General Comment No. 14 (2000), para. 7. See also Marks, “The emergence and scope of the human right to health,” p. 107.

¹¹³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, (New York, Oxford University Press, 2007), p. 104. See also Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement: An Interpretation of the TRIPS Agreement in Relation to the Right to Health*, (Leiden, Netherlands, Martinus Nijhoff, 2012), p. 25.

States' actions must be decisive for "the creation of conditions which would assure to all medical service and medical attention in the event of sickness."

In illustrating the meaning of the terms enshrined in the provision, the United Nations Committee on Economic, Social and Cultural Rights (hereafter, Committee on the ESCR) has provided an authoritative, albeit non-binding, interpretation of article 12. The Committee on the ESCR has explained that the steps to be taken refer to, among other things, the provision of access to essential medicines.¹¹⁴ Accordingly, while critical attributes of the right to health include medical service in the event of sickness and the prevention, treatment and control of diseases, which are included in article 12(2)(d) of the ICESCR, the realisation of the right to health hinges fundamentally upon ensuring access to medicines (here, biologics).¹¹⁵ Accordingly, when article 12(2)(c) is read in tandem with article 12(2)(d), one can conclude that access to medicine (e.g., biologics) is an indispensable component of the right to health "both as treatment for epidemic and endemic diseases and as part of medical attention in the event of any kind of sickness."¹¹⁶ In this context, while access to biologics in general is a basic human right,¹¹⁷ access to essential biologics as "defined by the WHO's Action Program on Essential Medicines"¹¹⁸ is a central component of the right to health, since it requires immediate actions from the State Parties.¹¹⁹

When this is contextualized within the State Parties to the CPTPP, of the eleven CPTPP nations, eight (Australia, Canada, Chile, Japan, Mexico, New Zealand, Peru and Vietnam) are already Parties to the ICESCR. The remaining three nations (Brunei, Malaysia and Singapore) have ratified other international human rights instruments that cover the general right to health as well as biologics.¹²⁰ Therefore, the accession of the CPTPP Parties to international human-rights instruments implies that the Parties have an obligation to ensure access to biologics.¹²¹ Parties to the CPTPP are bound to fulfil, protect and respect access to this class of medicine. As an integral part of this obligation, the Parties are required to ensure not only accessibility to biologics but also their availability, acceptability and high quality.¹²² In this context, while

¹¹⁴ Hans V. Hogerzeil et al., "Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?," *Lancet*, No. 368 (2006), p. 305. In the same vein, the Alma-Ata Declaration proclaims that "the attainment of the highest possible level of health is a most important world-wide social goal." The provision of essential medicine is one of the eight listed components of Primary Health Care.

¹¹⁵ Paul Hunt and Rajat Khosla, "The human right to medicines," *SUR-International Journal on Human Rights*, No. 8 (June 2008), p. 100.

¹¹⁶ Alicia E. Yamin, "Not just a tragedy: Access to medications as a right under international law," *Boston University International Law Journal*, No. 21, (2003), p. 336.

¹¹⁷ United Nations Human Rights Council (UNHRC), "Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," A/HRC/32/L.23/Rev.1 (30 June 2016), p. 1. See also Hunt and Khosla, "The Human Right to Medicines," p. 102. Paul and Rajat have argued that access to essential and non-essential medicines is part of the right to health.

¹¹⁸ See the Committee on ESCR, General Comment No. 14 (2000), para. 12(a). See also Hogerzeil et al., "Is access to essential medicines enforceable through the courts?," p. 305.

¹¹⁹ Similarly to the WHO, States also have national Essential Medicines Lists (EMLs). National EMLs are often developed on the basis of the WHO EML.

¹²⁰ For instance, all of the CPTPP countries have ratified the Convention on the Right of the Child. Article 24 of the Convention states that the Parties "recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health," taking into account both the child's biological, social, cultural and economic preconditions and the State's available resources.

¹²¹ See MacDonald, *The Global Human Right to Health*, p. 310.

¹²² See the Committee on ESCR, General Comment No. 14 (2000), para. 12. See also Yamin, "Not just a tragedy," p. 337. See also Jennifer Sellin, "Justiciability of the right to health-access to medicines: The South African and Indian experience," *Erasmus Law Review*, vol. 2, No. 4 (2009), p. 448. See again Jennifer Sellin, *Access to Medicines: The Interface between Patents and Human Rights. Does One Size Sit All?* (Cambridge, U.K., Intersentia, 2014), p. 121. See also Hestermeyer, *Human Rights and the WTO*, p. 130. This means that the design of human right to health in general and the right to medicine in particular are guided by key human rights principles and standards. See also the Committee on ESCR General Comment No. 14 (2000), para. 12. Simply stated, the realization of the right to

“accessibility” means, among other things, that biologics must be affordable to all, including those who live in poverty,¹²³ “availability” implies the timely availability of a “sufficient quantity” of biologics.

Bearing in mind these issues, the next section will examine whether and how the rule on test data, if unsuspending, will preclude access to biologics.

medicines needs adherence to “rigorous principles and standards,” *inter alia*, to the availability, accessibility, acceptability and quality (commonly recognized as AAAQ) of medicines.

¹²³ *Ibid.*; the Committee on ESCR, General Comment No. 14 (2000), para. 12(b). See also Philippe Cullet, “Patents and medicines: The relationship between TRIPS and the human rights to health,” *International Affairs* vol. 79, No. 1 (2003), pp. 148–149.

5. TPP'S TEST DATA EXCLUSIVITY: DETERRING THE REALIZATION OF ACCESS TO BIOLOGICS

When the rule on test data with respect to biologics is inspected through the lens of TRIPS and/or the normative content of the international human-rights instruments discussed above, the provision may preclude access to biologics, as it impedes, among other things, the timely availability and accessibility (i.e., affordability) of biologics.¹²⁴ In part by limiting the use of the policy space or “flexibilities” available for WTO Members to implement the provisions of the TRIPS Agreement,¹²⁵ the rule may raise the price of biologics. As the provision stands now, there is a particular concern that it may limit the flexibility of TRIPS, which enables the use of or reliance on test data to be submitted for the purpose of reference biologics. As such, if third parties (such as biosimilar producers) consider producing or marketing identical or similar¹²⁶ biologics, they may not be able to rely on previously submitted test data. Relatedly, although the provision does not identify the third party to which it refers, it can be surmised from the assertions made earlier that it is often biosimilar or any other producers that rely on the test data of reference biologics. This theory is strengthened by footnote 52 to article 18.50, which stipulates that a Party is obligated to ban a third party (a biosimilar producer, a compulsory licensee or any other party) that intends to market an identical or similar biologic on the basis of test data already submitted.¹²⁷ Footnote 52 to article 18.50(1)(a) clarifies the phrase “similar pharmaceutical product” by stating that a certain pharmaceutical product is similar to one previously approved

if the marketing approval, or, in the alternative, the applicant’s request for such approval, of that similar pharmaceutical product is based upon the undisclosed test or other data concerning the safety and efficacy of the previously approved pharmaceutical product, or the prior approval of that previously approved product.

In light of article 18.51, it can be inferred that, while the provision mainly targets biosimilar producers, any third party is banned temporarily from relying on existing test data. An HRA is required to protect the data not only against third parties but also against itself (e.g., its own actions) in cases where it approves identical or similar medicines. This provision is aimed at ensuring the right to biologics.¹²⁸

Given this hurdle, it may be important to ask whether there is any other available option on the basis of which the CPTPP Parties will be able to fulfil, protect and respect access to biologics during the period of exclusivity. The answer may lead us to two divergent, yet both impractical, alternatives. The first, unlikely, alternative on the basis of which a Party may receive an application from a third party is when developers of test data give permission to an HRA.¹²⁹ The

¹²⁴ For a similar conclusion regarding test data exclusivity in general, see Shaikh, *Access to Medicine versus Test Data Exclusivity*, p. 4.

¹²⁵ See also Rochelle C. Dreyfuss, “Harmonization: Top down, bottom up—And now sideways? The impact of the IP provisions of megaregional agreements on third party states,” *New York University School of Law, IILJ Working Paper 2017/2* (June 2017), pp. 11–12.

¹²⁶ See Footnote 52 to article 18.50 of the TPP IPRs Chapter.

¹²⁷ See article 18.50(1)(a)(i), which specifically prohibits the reliance on test data.

¹²⁸ See the United Nations Secretary-General’s High-Level Panel on Access to Medicines, “Promoting Innovation and Access to Health Technologies,” p. 5. The UNHLP has discussed the overall effects of data exclusivity by alleging that exclusivity is a legal regime that prevents a national HRA from relying on the test data submitted.

¹²⁹ Read articles 18.50(1)(b) and 18.51 together.

cumulative reading of articles 18.50(1)(b) and 18.51 is that a Party “shall not permit third persons, without the consent of the person that previously submitted such information.”¹³⁰ From the *a contrario* reading of the phrase, one may surmise that the Parties can market similar or the same biologics if they can secure the consent of the developers of the test data. Still, though getting permission from the developers may not be impossible, it may be impractical: from the standpoint of the developers, which often opt to monopolize their test data, it may not make sense to facilitate competition that reduces their market share. This lack of consent may ultimately prevent timely access to biologics, as the Parties’ rights are relegated to an auxiliary position due to their inability to take measures to rely on or use of the biologic.¹³¹

Apart from prohibiting the reliance on test data, the consent requirement also obligates Parties (such as Brunei, Australia, Malaysia, New Zealand, Peru and Vietnam) to abstain from even receiving an application intended only for approval and not necessarily for marketing. In particular, the phrase “the applicant’s request for such approval,” as included in footnote 52 to article 18.50, shows that, regardless of whether the application is made for the purpose of marketing, the Parties are barred from receiving even an application that aims simply to approve a cost-cutting biologic. As stated earlier, this prohibition leads to inaccessibility and a lack of timely availability of biologics¹³² since a Party may not be able to expedite the entry of biosimilar products into the marketplace. The timely availability of biologics may, among other things, require the production of biosimilars prior to the expiration of the protection (the test data exclusivity or patent). This is because, though biosimilars may not be placed in the market prior to the expiration of exclusivity, it might be necessary to produce or approve biosimilar products so the medicine can be expedited and placed in the market immediately upon the expiration of a reference biologic’s exclusivity. For this to be possible, a Party must authorize a third party to manufacture this class of low-priced medicine in advance.

The prevention of access to the test data, aside from impeding the availability and accessibility of biologics during the period of test data exclusivity, may have consequences even after the period of test data exclusivity. Third parties may be authorized with reference to the originator’s test data only once eight years of test data exclusivity have elapsed. This tendency, as noted, may postpone the entry of affordable biologics into the market.¹³³ Beyond the eight-year fixed period of exclusivity, however, there may remain repercussions for the right to biologics. This is not without reason: according to article 18.51, third parties may begin to rely on the test data once the period of exclusivity expires.¹³⁴ This means that the production process and other regulatory issues required to place biosimilars in the market must begin after eight years have elapsed. Given the length, especially for biosimilars, of the production process (the time interval

¹³⁰ Ibid.

¹³¹ Although Parties to the ICESCR and other international human rights instruments have the right to rely on all appropriate means to ensure access to biologics, the reliance on or use of test data, which can be a constitute part of an appropriate means, is difficult in the absence of the consent of test data generators.

¹³² United Nations Human Rights Council, “Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,” A/HRC/RES/12/24, (12 October 2009), para. 5. The resolution underlines that, although IPRs are important for promoting innovation, they have a negative spillover effect on economic accessibility.

¹³³ Under this situation, people might be forced to pay out of pocket to cover the costs of medication. This can even be the case in countries that provide a health insurance system. This is because the Parties to the TPP may not cover the entire costs due to the high price of biologics. Out-of-pocket payments are among the barriers to the full enjoyment of the right to biologics. See also Report to the United Nations General Assembly, “Right of everyone to the enjoyment of the highest attainable standard of physical and mental health,” A/71/304 (5 August 2016), p. 20.

¹³⁴ For instance, TRIPS does not prohibit preparation for the purpose of entering into a market. For a similar conclusion see Carlos M. Correa, “Expanding Patent Rights in Pharmaceuticals: The Linkage between Patents and Drug Registration”, in *The Development Agenda: Global Intellectual Property and Developing Countries*, Neil Weinstock Netanel, ed. (Oxford, U.K., Oxford University Press, 2009), p. 247.

between the expiry of exclusivity and the market entry of a biosimilar), a biosimilar's entry into the market may be further delayed.¹³⁵ Provided that a reference biologic is not patent-protected, this process may force the Parties to place biosimilars in the market only after more than eight years have expired.¹³⁶ Thus, despite the provision of eight years of test data exclusivity under both Options A and B, the protection given has implications for both exclusivity and post-exclusivity (marketing exclusivity).¹³⁷ Simply put, even after the eight-year period of exclusivity expires, what this paper calls *disguised exclusivity (DE)* persists, as biosimilars may not be able to enter into the marketplace immediately.¹³⁸ Article 18.51 imposes no obligation on a Party to process a generic biologic swiftly.

As seen above, given that article 18.51 precludes the reliance on or use of test data, one impractical option available to HRAs is the consent of a generator of test data for a reference biologic. Article 18.51 also features another, albeit unlikely, scenario on the basis of which an application (simply for approval, not marketing) for a generic biologic might be accepted.¹³⁹ The cumulative reading of articles 18.50(1)(a)(i and ii) and 18.51 demonstrates that HRAs are prohibited from receiving an application from a biosimilar producer *only* if the producer's plan to market that particular biosimilar is based on test data already submitted for the purpose of a reference biologic.¹⁴⁰ The *a contrario* reading of this suggests that article 18.51 does not prohibit a Party from accepting an application if a third party reproduces *its own* test data.¹⁴¹ Still, the development of full-scale test data may further roll back the endeavour to ensure access to biologics. In this context, the additional rollback may develop from many factors.

The first line of argument relies on a comparison between biosimilars and the generic versions of small-molecule medicines. It is rare that producers of generics are required to generate a clinical trial in order to obtain marketing approval.¹⁴² These producers are, however, often required to conduct studies to show "bioequivalence" (proof that a generic works the same way

¹³⁵ For a similar conclusion see Burcu Kilic, "Data exclusivity in the Regional Comprehensive Economic Partnership (RCEP)" (2016), p. 2.

¹³⁶ For instance, the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), another mega-regional agreement, provides test data and market exclusivity under article 20.29(2)(a)(b). In this regard, it provides eight years of exclusivity (test data and marketing). It gives the manufacturer of a biosimilar "a window of 2 years to obtain marketing approval (using the data of the originator pharmaceutical rights owner)." By doing so, it at least attempts to avoid disguised exclusivity. See also Thomas Cottier et al., "The prospects of TRIPS-plus protection in future mega-regionals," in *Mega Regional Trade Agreements*, Thilo Rensmann, ed. (Cham, Switzerland, Springer International Publishing AG, 2017), p. 206.

¹³⁷ This is because there are other regulatory requirements that biosimilar producers are expected to meet after the expiration of test data exclusivity.

¹³⁸ For instance, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) has argued that accepting an application from competitors for the purpose of approval is contrary to the TRIPS Agreement. It specifically argued that a decision like *Bayer Inc. v. Canada* is inconsistent with article 39(3) of TRIPS. See International Federation of Pharmaceutical Manufacturers & Associations, "Encouragement of New Clinical Drug Development: The Role of Data Exclusivity," IFPMA (2000), p. 8.

¹³⁹ See articles 18.50(1)(a)(i and ii) and 18.51 of the TPP's IPRs chapter.

¹⁴⁰ The phrase, "to market the same or a similar product on the basis of information or the marketing approval granted to the person that submitted such information," as embodied in article 18.50, illustrates that a Party is prohibited from receiving an application from a third party if that application is made on the basis of the test data of a reference biologic.

¹⁴¹ This approach requires biosimilar developers to conduct a full-scale test data similar to that which has already been submitted for a reference biologic. Even if the provision (article 18.51) allows the Parties to accept an application, provided that third parties develop their own test data, by and large, biosimilar companies could not conduct full-scale test data for the purpose of obtaining marketing rights. Among other reasons, this relates to the financial status of most cost-cutting biologics. Thus, the development of a full scale test data does not also promote the right to biologics.

¹⁴² See Jean-Louis Prugnaud and Jean-Hugues Trouvin, eds., *Biosimilars: A New Generation of Biologics*, (Paris, Springer-Verlag France, 2013), p. 2.

as its reference medicine).¹⁴³ A generic producer that can demonstrate bioequivalence is normally expected to rely on the test data already submitted for the purpose of a reference small-molecule medicine, provided that test data exclusivity does not apply.¹⁴⁴ The production of generic versions of small-molecule medicines differs from that of biosimilars, as biosimilar producers are required to produce rigorous clinical proof¹⁴⁵ to obtain marketing approval.¹⁴⁶ This is because biologics are complex with regard to both their structure and their manufacturing process. The World Health Organization (WHO) Expert Committee on Biological Standardization states that “an approach established for a generic medicine is not suitable for development, evaluation and licensing” (i.e., marketing) of biosimilar medicines.¹⁴⁷ Therefore, the HRAs of the CPTPP countries (e.g., Canada and Australia) require clinical trials. It is often after conducting such studies that biosimilar producers seek to rely on the test data of a reference biologic.¹⁴⁸

The requirement that biosimilar producers conduct robust clinical studies results in a higher price for biosimilars than for generic versions of small-molecular medicines.¹⁴⁹ Nonetheless, irrespective of their high prices, article 18.51 requires the Parties to receive an application from third parties if, and only if, they repeat the test data already produced for the purpose of a reference biologic.¹⁵⁰ Therefore, this reproduction is unacceptable not only from an ethical point of view,¹⁵¹ but also because the reproduction may increase the price of biosimilars substantially¹⁵² and thereby make them less affordable.¹⁵³ Though biosimilars are normally meant to be cheaper, thereby enhancing the accessibility and availability of biologics,¹⁵⁴ the

¹⁴³ The World Health Organization Expert Committee on Biological Standardization, “Guidelines on evaluation of similar biotherapeutic products (SBPs),” WHO Technical Report Series No. 977 (2013), p. 3. See also Angelina S. Godoy, *Of Medicines and Markets: Intellectual Property and Human Rights in the Free Trade Era*, (Palo Alto, California, Stanford University Press, 2013), p. 23.

¹⁴⁴ As a case in point, the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act of 1984) in the United States got rid of the requirement for such a redundant clinical trial. See Section 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act of 1984).

¹⁴⁵ For instance, the European Medicines Agency’s (EMA) Guidelines on Biosimilars requires producers to demonstrate comparative clinical trials. See also Francisco J. Esteva et al., “A randomised trial comparing the pharmacokinetics and safety of the biosimilar CT-P6 with reference trastuzumab,” *Cancer Chemotherapy and Pharmacology*, vol. 81, No. 3, (12 January 2018), p. 2. For instance, while the U.S. Food and Drug Administration (FDA) requires at least one comparable clinical pharmacokinetics (PK) study to demonstrate similarity between a reference and biosimilar, the EMA also requires a comparable clinical pharmacokinetics study. See also Prugnaud and Trouvin, *Biosimilars: A New Generation of Biologics*, p. 2; Steven Simoens, “Biosimilar medicines and cost-effectiveness,” *ClinicoEconomics and Outcomes Research* (2011), p. 33. As Simoens has argued, in comparison to generics, which often show bioequivalence to a reference small-molecule medicine, biosimilar developers are often required to conduct at least phase I and III clinical trials.

¹⁴⁶ See The World Health Organization Expert Committee on Biological Standardization, “Guidelines on evaluation of similar biotherapeutic products (SBPs),” p. 3. See also Germán Velásquez, “The international debate on generic medicines of biological origin,” South Centre Research Paper no. 82 (November 2017), p. 13.

¹⁴⁷ The World Health Organization Expert Committee on Biological Standardization, “Guidelines on evaluation of similar biotherapeutic products (SBPs),” p. 3.

¹⁴⁸ For the experience in Australia, see Ruth Lopert et al., “Proposals for extending data protection for biologics in the TPPA: Potential consequences for Australia,” Submission to the Department of Foreign Affairs and Trade (15 December 2014), p. 3.

¹⁴⁹ This scenario may imply that, when compared to biosimilars, access to generics is subject to a lesser burden. This does not necessarily mean, however, that access to generics is easily achievable.

¹⁵⁰ See articles 18.50 (1)(a)(i&ii) and 18.51 of the TPP’s IPRs chapter.

¹⁵¹ See World Medical Association (WMA) Declaration of Helsinki, “Ethical Principles for Medical Research Involving Human Subjects,” adopted by the 18th WMA General Assembly, Helsinki, Finland (June 1967), para. 6.

¹⁵² WHO, “Briefing note: Access to medicines,” p. 1.

¹⁵³ See Godoy, *Of Medicines and Markets*, p. 24.

¹⁵⁴ As a case in point, some analyses show that in the U.S., “biosimilars will reduce direct spending on biologic drugs by \$54 billion from 2017 to 2026, or about 3 percent of the total estimated biologic spending over the same period.”

requirement to reproduce the test data may nullify this benefit. Therefore, article 18.51, as it stands now, may interfere with the CPTPP Parties' ability to ensure access to biologics. While this interference may be extensive in countries like Brunei, which does not recognize test data exclusivity within its domestic jurisdiction, the repercussions can also spread disproportionately to other Parties to the CPTPP.

This may lead one, then, to ask whether there is a public health exception to counterbalance the implications of the provision. Article 18.6 of the IPRs chapter provides public health understandings agreed upon by the TPP Parties.¹⁵⁵ In particular, the provision makes reference to access to medicine-related instruments adopted under the auspices of the WTO. For example, article 18.6(1)(a) states that "the Parties affirm their commitment to the Declaration on TRIPS and Public Health."¹⁵⁶ Additionally, article 18.50(3) states that the Parties "may take measures" for the purpose of access to biologics. When these provisions are assessed through the lens of the obligations imposed on the Parties by article 18.51, the provisions relating to public health may not provide an effective response to the impediments (e.g., the lack of affordability or timely availability) accruing from article 18.51. This argument may stem from the nature of rights as well as obligations integrated into the provisions (articles 18.50 and 18.51 *vis-à-vis* public health measures). Although article 18.51 imposes an obligation on the Parties to deliver test data exclusivity, on the other hand, the cumulative reading of articles 18.50(3) and 18.51(1)(b)(i) affirms the right of the Parties to use public-health measures.

Still, a comparative and thorough reading of the provision (articles 18.6 and 18.51(1)(b)(i)) and the rule on test data exclusivity fails to explain how biologics can be easily accessed in the presence of test data exclusivity. Article 18.6 (a rule on public health understanding) simply identifies the WTO Members' rights, which help Members use or rely on said public health understandings. Still, the provision, aside from reiterating the pro-medicine rights integrated under TRIPS and the Doha Declaration,¹⁵⁷ fails to stipulate how the Parties can implement such rights in the presence of a new and robust obligation created through article 18.51(1).¹⁵⁸ Although article 18.50(3) states that the Parties "may take measures," on the other hand, the provision stipulates that the Parties "shall provide" (rather than, for example, "may adopt") test data exclusivity. As such, although the provision makes cross-reference to the TRIPS provision,

See Andrew W. Mulcahy et al., "Biosimilar cost savings in the United States: Initial experience and future potential," RAND Corporation (2017), p. 1.

¹⁵⁵ See article 18.6 of the TPP's IPRs chapter.

¹⁵⁶ See article 18.6(1)(a). It reads "The Parties affirm their commitment to the Declaration on TRIPS and Public Health. In particular, the Parties have reached the following understandings regarding this Chapter: (a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all. Each Party has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

¹⁵⁷ The United Nations Secretary-General's High Level Panel on Access to Medicines, for instance, recommended that Members States to the WTO "should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies" (i.e., medicines). See the United Nations Secretary-General's High-Level Panel on Access to Medicines, "Promoting Innovation and Access to Health Technologies," p. 27. See also Sellin, *The Interface between Patents and Human Rights*, p. 286.

¹⁵⁸ For a similar conclusion, see also Artecona and Plank-Brumback, "Access to medicines and incentives for innovation: The balance struck in the Trans-Pacific Partnership (TPP)," p. 26.

the flexibilities vested in TRIPS are mitigated by the adoption of a new robust obligation in article 18.51.¹⁵⁹

Cognizant of the above situation and provided that the CPTPP Parties must overcome such a hindrance, the Parties, in addition to taking other actions, should adopt and use some relevant flexibilities to implement the public health understandings. One potential area of leeway for implementing the public health understanding could be the adoption and effective use of flexibilities, such as the one included under article 91 of Chile's Law 19.996. In this sense, the Parties should be able to terminate test data exclusivity for reasons of, among other things, public health and public non-commercial use. The Parties should explicitly state also that test data exclusivity can be terminated if the pharmaceutical product (here, biologics) is subject to a compulsory license, as included under article 31 of the TRIPS Agreement. As the TPP's test data rule stands now, however, the provision can indeed limit access to biologics.

¹⁵⁹ See Matthew Rimmer, "The Trans-Pacific Partnership: Patent Law, Public Health and Access to Essential Medicines," Submission to Australia's Senate Foreign Affairs, Defence and Trade References Committee (October 2016), p. 62.

6. CONCLUSION

Though biologics provide treatment for rare and chronic diseases like leukaemia, which result in human death, the benefit of this class of medicine can be enjoyed only if biologics are economically accessible and adequately available in a timely manner to all. From the stance of the TPP's IPRs chapter, economic accessibility and the timely availability of biologics might be restricted if the Parties to the CPTPP decide to revoke, for any reason, the suspended provision on test data. From this perspective, the negative repercussions of access to biologics may accrue, since the provision could potentially restrain the Parties' flexibility as enshrined in, among other places, article 39(3) of the TRIPS agreement. In this regard, although the TRIPS provision enables the CPTPP Parties to use and/or rely on the test data submitted for the purpose of marketing a reference biologic, the TPP's article 18.51 may limit the reliance on such flexibility before the exclusivity on a reference biologic expires.

Going a step further, the limitation imposed on the Parties may also empower a reference biologic producer to enjoy exclusivity even after its period of test data exclusivity has expired. This advantage, which this paper calls *disguised exclusivity (DE)*, results from the time interval between the expiration of test data exclusivity on a reference biologic and the marketing approval of a biosimilar medicine. *Disguised exclusivity* may further delay the market arrival of cost-cutting biosimilars. Similarly, test data exclusivity could render a compulsory license meaningless without a clear opt-out, like the provision included in article 91 of the Chilean Law 19.996.

Furthermore, the provision also forces third parties, such as biosimilar producers, to reproduce test data in order to obtain marketing approval during the period of exclusivity. Rerunning tests not only defeats the purpose of biosimilars (i.e., their affordability), it is also ethically unacceptable. Therefore, as article 18.51 stands now, revoking the rule on test data may preclude the timely availability and economic accessibility of biologic medicines.

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