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Test Data Protection in Free Trade Agreements (FTAS): A Barrier to Affordable Access to Medicines amid the Covid-19 Pandemic?

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ABSTRACT

Test data that is submitted by the originator to the national health regulatory agencies for the marketing authorization of a new drug or medicine is protected under Article 39.3 of the TRIPS Agreement. This test data protection regime is a debatable issue of Intellectual Property (IP) since TRIPS has not provided a comprehensive global standard of test data protection, rather it obligates the Member States to provide a minimum level of protection. Considering that Article 39.3 has established a regulatory floor of test data protection, developed countries with stronger research and development (R&D) based companies seek a greater level of protection. Accordingly, they are frequently entering into various FTAs with developing countries that include more specific models of test data protection, such as providing an exclusivity period for test data. This model of test data protection affects the affordable access to medicines in the least developed countries (LDCs) and developing countries with no or weaker pharmaceutical industries. This paper essentially evaluates the extent to which a country has obligations to protect test data under the selected two Free Trade Agreements (FTAs), namely the Australia-US FTA and the Agreement between the United States of America, the United Mexican States, and Canada (USMCA). The paper finally concludes that the provisions of those FTAs are considered to create obstacles to the entry of generic medicines into the market. However, in the context of the COVID-19 crisis, the provisions for test data protection in those FTAs can be circumvented.

Keywords: *Test data, Protection, Affordable access, Medicines, COVID-19.*

I. INTRODUCTION

When a new drug or medicine wants to enter the market, it needs to validate that it is safe and effective for use. This validity is provided by the national health regulatory agencies after scrutinizing the relevant information of clinical trials and the manufacturing processes.[3] The information or data that is submitted to the regulatory agencies are known as "test data". As the

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[3] Wael Armouti & Mohammad FA Nsour, *Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan under the US-Jordan Free Trade Agreement*, 17 Or. Rev. Int. Law 259, 263 (2015).

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health regulatory agencies determine the efficacy and safety of the medicine, they need this test data which is collected from clinical trials. But there is a concern from the innovator of the medicine who requires some sort of protection for those test data provided to the governmental agencies. Given the efforts, time, and investment of the originator of the medicines, the government is obliged to protect those data only "against disclosure" or "against unfair commercial advantage" subject to some limitations and exceptions including "public interest".[4]

The first international agreement which provided protection of test data is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 of the TRIPS agreement states:

> 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.[5]

The first sentence of this Article highlights the "obligation to protect against unfair commercial use", the second sentence stresses the "obligation to protect against the disclosure" of undisclosed test or other data. It seems that Article 39.3 has obligated the Member States to establish a minimum level of protection for test data without setting out a comprehensive global standard of test data protection. This has created an intense debate between the developing and developed countries. While the developed countries with robust pharmaceutical industries are in favour of providing greater protection of test data with an exclusive period of protection, the developing countries are in favour of providing a minimum standard of protection as greater protection may hamper affordable access to medicines in those countries.[6]

It has always been observed that since the TRIPS Agreement always provides a baseline for intellectual property (IP) protection, WTO Member States tend to enter into various free trade agreements (FTAs) between themselves. Going beyond the TRIPS, these FTAs have provided provisions with higher IP protection which are known as TRIPS-Plus provisions. For example, most of the FTAs contain data exclusivity instead of data protection, and some of them limit

[4] Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 (1) Am J Law Med 63, 81 (2012).
[5] TRIPS, art 39.3.
[6] Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46 Fla. St. U. L. Rev. 641, 653 (2019) [hereinafter "Yu"].

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the grounds for the issuance of compulsory licensing. Moreover, FTAs include the patent linkage provision, which links the marketing authorization of generic medicines with the patent status of innovator's medicine and refuses to permit the marketing authorization till the expiration of the patent.[7] Like the data exclusivity, patent linkage creates another barrier for the generic companies while entering the marketplace, thus affecting the availability of medicines. This additional protection for test data makes the question of test data protection and compulsory licensing relationship even more pressing. Against this background, one can raise strong concerns regarding the impact of these provisions of the FTAs which have a significant impact on access to medicine.

II. TEST DATA PROTECTION IN FREE TRADE AGREEMENTS (FTAS)

The TRIPS Agreement has created a "regulatory floor" for the protection of test data and allowed Members flexibility in adopting different approaches to protect the data submitted by the innovators for marketing authorization of their products. In this context, developed countries negotiated numerous free trade agreements (FTAs) to establish a heightened level of test data protection, such as data exclusivity. This paper will evaluate two FTAs: one is comparatively an old FTA "Australia-US FTA" and another is the latest FTA "United States–Mexico–Canada Agreement (USMCA)".

(A) Australia-US FTA

On 18 May 2004, Australia and the United States signed a bilateral free trade agreement - an agreement between the (then) 15th and first largest economies in the world.[8] The agreement (Australia-US FTA) has heightened the level of IP protection and enforcement. This FTA also sets a particular business template to produce medicines with higher IP protection. Therefore, it was a step by the US to establish a precedent for future trade agreements between the US and other nations. There are 12 articles on Intellectual Property Rights (IPRs) under chapter 17 in the AUS-US FTA. Article 17.1 laid down the general provisions saying that these are minimum levels of protection required by each member. Thus, members can provide additional protection for, and enforcement of, IPRs by incorporating provisions into their domestic laws which are consistent with the provisions of FTA.

a. Protection of Test Data

Inclusion of the principal tenets of data exclusivity in the AUS-US FTA was a strategy by the

[7] Wael Armouti, *Evolution of Data Exclusivity for Pharmaceuticals in Free Trade Agreements*, 76 South Centre Policy Brief 1, 3 (2020).
[8] United States–Australia Free Trade Agreement ('US-Australia FTA') (18 May 2004, 43I.L.M. 1248).

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US to set a new international standard on the protection of test data. Article 17.10 of the FTA requires Australia to set up a regime for test data protection that goes beyond what is required in Article 39.3 of the TRIPS.

Compared to the TRIPS agreement, Article 17.10 modified certain conditions in relation to the market protection eligibility which is dependent on protection against disclosure and there is no 'considerable effort' requirement. Instead of 'new chemical entities (NCEs)', the provision includes 'new pharmaceutical products'. Under Article 17.10 (c), a new product is defined as a product that does not possess a previously approved chemical entity. So, the definition excludes the patent novelty concept of new and no limitation of time for a product to be considered as new.[9] In addition, the provision requires parties to provide an extensive data exclusivity obligation, including the reliance on foreign marketing approval and extension of test data protection which goes beyond the patent expiration date.

Specifically, The Australia-US FTA provides for a five-year period of data exclusivity in pharmaceuticals and a ten-year period in agricultural chemicals.[10] During this period, the national regulatory authorities of both parties are prevented from using the test data submitted by the originator. Therefore, the generic companies cannot get marketing approval by referring to the test data submitted by the originator. The regulatory authority is thereby prevented from permitting the generic manufacturer until the expiry of the data exclusivity period or unless the generic applicants generate their own clinical test data which is not commercially viable and would also be unethical.[11]

According to Article 17.10.1 (c), the prescribed data exclusivity period extends in the case of test data that is submitted to a foreign regulator for marketing authorization. In that case, the five-year exclusivity period begins immediately from the date of foreign marketing approval or approval by the party, whichever is later.[12] For instance, X, an originator company, registered the drug ABC in the US but not in Australia. Hence, a generic manufacturer of the drug ABC cannot use the previously submitted test data by the originator company until the expiration of 5 years from the date of marketing approval. This means that the originator, as well as the generic version of the drug ABC, may not be available in Australia during this exclusivity period. This provision of Article 17.10. 1 (c) is commonly referred to as the "cross-border data

[9] Wael Armouti & Mohammad Nsour, *Data Exclusivity for Pharmaceuticals in Free Trade Agreements: Models in Selected United Sates Free Trade Agreements*, 40 HousJIntlL 105, 120 (2017).
[10] US - Australia FTA, art 17.10.
[11] Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. Intellect. Prop. Law Pract. 447, 453 (2011).
[12] US - Australia FTA, art 17.10.1(c).

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exclusivity provision" which goes beyond the TRIPs requirement.

Furthermore, Article 17.10.2 broadens the scope of protection by granting a three-year period of data exclusivity for new clinical information.[13] This new clinical information includes new uses of old chemical entities and new combinations or dosage forms as the provision expressly states that any information other than related to bioequivalency.[14] Finally, the Australia-US FTA extends the data exclusivity protection even after the patent expiration. As per Article 17.10.3, even in the event of patent termination earlier than the exclusivity period, parties should not alter the term of protection.

Article 17.1.2 of the Australia-US FTA acknowledges all the existing rights and obligations of the parties under all the multilateral agreements including the TRIPS. Since the Doha Declaration is regarded as "a subsequent agreement on the interpretation of TRIPS" under Article 31(3) (a) VCLT in the Australia-Plain packaging case, the declaration also comes under the purview of Article 17.1.2. The provision specifically states that- "The Parties affirm their existing rights and obligations with respect to each other under existing bilateral and multilateral agreements to which both Parties are party, including the WTO Agreement." This provision preserves the flexibility available under Article 39.3 of the TRIPS Agreement unless otherwise tightened by Article 17.1.1 of the Australia-US FTA.

b. Compulsory Licensing Restrictions

As the TRIPS Agreement has not imposed any restriction on the issuance of compulsory licenses, the Doha Declaration also provides freedom to the member countries to set up the grounds for the issuance of compulsory licenses.[15] However, the Australia-US FTA encompasses substantial constraints on the use of compulsory licenses.[16]

Under the compulsory licensing mechanism, governments of both parties can use or allow a third party to use the patent-protected product to produce or supply generic medicines in cases of "public non-commercial use, or of national emergency, or other circumstances of extreme urgency". This is stated in Article17.9.7.[17] Notably, the FTA does not define "national emergency or extreme urgency situations" or "public non-commercial use".[18] The 2001 Doha

[13] US - Australia FTA, art 17.10.2.
[14] *Ibid.*
[15] Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines—Coming to Grips with TRIPS: Conversion + Calculation*, 38 Journal of Law, Medicine and Ethics 520 (2010).
[16] Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 ChiKentLRev 1469, 1499–500. (2007) (noting that U.S. FTAs limit compulsory licensing beyond TRIPS requirements)
[17] Australia-US FTA, art 17.9.7.
[18] Pedro Roffe & Christoph Spennemann, *The Impact of FTAs on Public Health Policies and TRIPS Flexibilities*, 1(1-2) Int. J. Intellect. Prop. Manag. 75, 80 (2006).

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Declaration in this regard specifically acknowledges that "[each] Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency". By virtue of Article 17.1.2 and the Doha declaration, each party of the FTA can determine the grounds to be considered a "national emergency or other circumstances of extreme urgency".

It is highly arguable that the data exclusivity provision may impact a country's ability to issue a compulsory license.[19] As compulsory licenses offer affordable access to patent-protected medicines by opening the possibility of generic medicines, test data exclusivity provision may empower the right holder to inhibit the registration of such generics.[20] Data exclusivity may, therefore, hinder the marketing approval of the generic medicines if the originator companies refuse to share their test data. Such an outcome would undermine the objectives of TRIPS and the spirit of the Doha Health Declaration.[21]

Furthermore, The Australia-US FTA does not provide any interpretative guidance on the interaction between the compulsory licensing restrictions and data exclusivity. Specifically, the agreed principles in Annex 2-C to the FTA describe that parties are committed to "the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy."[22] So, the data exclusivity provision cannot impede a party's ability to provide affordable access to medicines and treatments through the use of the compulsory license or government use.

(B) United States-Mexico-Canada Agreement (USMCA)

Signed in November of 2018, the USMCA is a free trade agreement between the United States, Mexico, and Canada to replace the North American Free Trade Agreement (NAFTA).[23] On 19 June 2019, Mexico became the first among the negotiating parties to ratify it. Following the approval of the US House and the US Senate in December 2019, all the negotiating parties agreed to the revised version of the agreement.[24] Essentially, the USMCA is a revised and modernized version of NAFTA as some denote it as a 'NAFTA 2.0'.[25] The final version of the

[19] Meir Perez Pugatch, Intellectual Property, Data Exclusivity, Innovation and Market Access, in Negotiating Health: Intellectual Property and Access to Medicines 127 (Pedro Roffe et al. eds., 2006).
[20] Carlos M. Correa & Reto M. Hilty, Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law 190 (Springer Nature 2022).
[21] Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (Doha, 14 November 2001, WT/MIN (01)/ DEC/ 2).
[22] US-Australia FTA, annex 2-C, art 1(c).
[23] Ana Swanson & Jim Tankersley, 'Trump Just Signed the U.S.M.C.A. Here's What's in the New NAFTA' *The New York Times* (New York, 01 July 2020) <https://www.nytimes.com/2020/01/29/business/economy/usmca-deal.html> accessed 28 March 2022.
[24] Protocol of Amendment to the USMCA (10 December 2019).
[25] Ronald Labonté *et al.*, *USMCA (NAFTA 2.0): tightening the constraints on the right to regulate for public health*,

agreement came into effect on 1 July 2020.[26]

Out of 34 chapters, chapter 20 specifically deals with the protection and enforcement of intellectual property rights.[27] The objective underlying the provisions on IPRs under chapter 20 reads as follows:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[28]

Remarkably, this objective is virtually identical to the objectives stated in Article 7 of the TRIPs agreement. Chapter 20 of the USMCA contains ninety provisions and two of those directly related to the test data protection: (i) for agrochemical products (Article 20.45)[29] and (ii) for pharmaceutical products (Article 20.48).[30] Interestingly, a number of USMCA provisions are closely based on the CPTPP, particularly the provisions on test data protection for agrochemical, biological, and pharmaceutical products.[31] In some cases, USMCA exceeded the obligations of CPTPP as the provisions regarding test data protection have been suspended in CPTPP.[32]

a. Protection of Test Data

Articles 20.45 and 20.48 specifically address undisclosed test or other data protection. In the case of marketing authorization for a new agrochemical product, USMCA member states may require the submission of undisclosed test or other data regarding the safety and effectiveness of that product.[33] For such test or other data, member states are required to provide a minimum of 10 years of protection from the date of national marketing approval. In addition, USMCA parties are prevented from using the submitted test data to issue marketing approval in favour of a third party to produce generic products during that period. The term of protection for the test or other data also extends to the data coming from a foreign country but for that, evidence

15(1) Globalization and Health 1 (2019)

[26] LESLIE ALAN GLICK, THE UNITED STATES-MEXICO-CANADA AGREEMENT (USMCA): LEGAL AND BUSINESS IMPLICATIONS (Wolters Kluwer 2020).

[27] Agreement between the United States of America, the United Mexican States, and Canada (USMCA) (30 November 2018) ch 20.

[28] *Id* art 20.2.

[29] *Id* art 20.45

[30] *Id* art 20.48.

[31] Yu, *supra* note 4, 681.

[32] Id at 682.

[33] USMCA, art 20.45.

of the foreign marketing approval has to be shown to the party.[34]

Regarding the new pharmaceutical products, USMCA establishes a similar kind of protection but the term of protection is reduced from ten to five years counting from the date of first national marketing approval.[35] The provision also covers the "reliance" issue meaning that marketing approval is not granted based on the previously submitted data.[36] In other words, the generic companies cannot rely on the previously submitted test data by the originator company for marketing approval to produce generic medicines. As Article 20.48 provides protection for new pharmaceutical products, the definition of a "new pharmaceutical product" is stated in Article 20.49 as a "pharmaceutical product that does not contain a chemical entity that has been previously approved in that Party".[37]

Compared to the test data protection concept contained in Article 39.3 of the TRIPS Agreement, the USMCA established a regulation exclusivity regime.[38] This data exclusivity regime creates a barrier that impedes affordable access to medicine and ultimately will have adverse repercussions on public health.

b. References to the Doha Declaration

The USMCA acknowledges the commitments of the parties to the TRIPS and the 2001 Doha health declaration.[39] In this regard, the USMCA parties have reached the following understandings:

> (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

[34] *Id* art 20.45.2.
[35] *Id* art 20.48.1.
[36] *Ibid.*
[37] *Id* art 20.49.
[38] Máté Hegedus-Gaspar, *Data exclusivity for biologics–an emerging multilateral standard?*, (2020) UC Research Repository, 47 <http://dx.doi.org/10.26021/10397> accessed 23 March 2022.
[39] USMCA, arts 20.6 (Understandings Regarding Certain Public Health Measures) and 20.1 (stating that "Declaration on TRIPS and Public Health means the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), adopted on November 14, 2001").

> represent a national emergency or other circumstances of extreme urgency.
> [40]

In addition, Article 20.48.3 specifically mentions that the provision concerning test data protection for new pharmaceutical products under Article 20.48 will not have an impact on the measures taken by the party to protect public health. It reads:

> Notwithstanding paragraphs 1 and 2, a Party may take measures to protect public health in accordance with:
>
> (a) the Declaration on TRIPS and Public Health;
>
> (b) any waiver of a provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or
>
> (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.[41]

It means that notwithstanding articles 20.48.1 and 20.48.2, "a party may take measures to protect public health in accordance" with the Doha Declaration.[42] Looking at the ordinary meaning of "public health", it means "the health of the population as a whole, especially as monitored, regulated, and promoted by the state."[43] As stated earlier that Article 20.6 (a) of the USMCA provided a reference to public health, this can be used as further clarification on the meaning of "public health provisions". The wording of "public health" in that provision referred to "national Emergencies" and "circumstances of extreme urgency". This suggests that the Doha Declaration can provide interpretative guidance to define "public health". The 2001 Declaration commences with the text: "We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."[44] The use of these words suggest that the one purpose of Article 20.48.3 is to permit developing and least developed countries to facilitate access to medicines in order to tackle grave public health problems.

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[40] *Id* art 20.6.
[41] *Id* art 20.48.3.
[42] *Id* art. 20.48.3
[43] Oxford Lexico, 'public health', *Oxford English and Spanish Dictionary, Synonyms, and Spanish to English Translator* < https://www.lexico.com/en/definition/public_health> accessed 27 March 2022.
[44] Doha Declaration, art 1.

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Furthermore, the wording of "measures" in Article 20.48.3 "a Party may take measures to protect public health in accordance with the Doha Declaration" suggests the application of the Doha Declaration in this provision. Para 5(b) of the Declaration in turn provides that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[45] Based on this, it can be said that governments of the parties can issue a compulsory license over test data for pharmaceutical products in order to tackle public health emergencies including epidemics. Compulsory licenses, therefore, can be issued by the governments to permit specific generic manufacturers to use the earlier clinical trial data submitted by the originator company after providing the originator an adequate remuneration.

Considering the severity and consequences of COVID-19, no one can deny it as a public health emergency. Hence, the data exclusivity regime in the USMCA is not a bar to issuing compulsory licenses in response to the public health crisis such as the COVID-19 pandemic.

III. CONCLUSION

It has been seen that after the TRIPS Agreement, IP law has shifted its focus on FTAs where a wide range of IP issues are covered. Those FTAs mostly provide a higher level of IP protection than the TRIPS Agreement. This paper has endeavored to put some light on the test data protection obligations of a country in the two selected FTAs- the Australia-US FTA and the USMCA. Considering that Article 39.3 has established a minimum level of test data protection, developed countries with stronger R&D-based companies seek a greater level of protection. Accordingly, they are frequently entering into various FTAs with developing countries that include more specific models of test data protection, such as providing an exclusivity period for test data.

This paper has delved into the test data protection commitments under two major FTAs such as the Australia-US FTA and the USMCA. Both the FTAs contain data exclusivity instead of data protection. While the Australia-US FTA provides for a five-year period of data exclusivity in pharmaceuticals, the USMCA provides for a minimum of 10 years of protection. Thereby, the provisions of those FTAs are considered to create obstacles to the entry of generic medicines into the market. However, in the context of the COVID-19 crisis, there are some TRIPS equivalent limitations in those FTAs. On the one hand, by virtue of Article 17.1.2 of the Australia-US FTA and the Doha Declaration, each party of the FTA can determine the grounds to be considered a "national emergency or other circumstances of extreme urgency". Thus, the

[45] *Id* para 5(b).

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parties of the Australia-US FTA can issue compulsory licenses by considering the pandemic as a national emergency. On the other hand, based on Article 20.48.3 of the USMCA, it is contended that governments of the parties can issue a compulsory license over test data for pharmaceutical products in order to tackle public health emergencies like the COVID-19 pandemic.

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