INTERNATIONAL COMMITMENTS FOR TEST DATA PROTECTION AND THEIR LIMITS IN THE CONTEXT OF ACCESS TO MEDICINES AMID A PANDEMIC SITUATION: THE CASE OF COVID-19 PANDEMIC

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ABSTRACT

Test data protection for the data that is submitted to governments by the originator of medicine is a contentious issue of intellectual property. The need for the protection of test data arises when the national authorities require the test data from the originator companies for the marketing authorization of medicinal products. The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS"), under Article 39.3, has provided an international standard of test data protection. This protection provision of test data creates an additional layer of protection for the medicine irrespective of patent protection, whereby it controls the affordability and accessibility of life-saving drugs. While TRIPS Article 39.3 obligates World Trade Organization (WTO) Members to protect pharmaceutical test data against "unfair commercial use" and "disclosure," the Agreement's inherent flexibilities-particularly its public health safeguards and national security exceptions-provide critical pathways to override these obligations during

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pandemics. This paper uniquely argues that the COVID-19 crisis (and future pandemics) constitutes an "emergency in international relations" under TRIPS Article 73(b)(iii), enabling states to suspend test data protection to expedite access to medicines.

KEYWORDS: *intellectual property, medicines, national security exceptions, pandemic, pharmaceutical test data*

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I. INTRODUCTION

A new medicine or drug is authorized to enter the market only after the national health regulatory agencies have validated its efficacy and safety. The regulatory bodies ensure that the medicine is effective and safe for use, and they validate this based on the pertinent information relating to clinical trials as well as the manufacturing processes. Later, when a second entrant applies for marketing authorization for the same medicine, the relevant health regulator can rely on the previously submitted data by the originator (first entrant) and approve the equivalent medicine. Therefore, generic companies can easily obtain the marketing approval for the generic medicines only by relying on the information submitted by the innovator companies. This approach facilitates the generic entrants to enter the market without the economic burden of producing their own test data. As a result,

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generic medicines have been able to contribute significantly to the accessibility and affordability of drugs.

From the beginning, research and development (hereinafter "R&D") based companies are not in favour of data reliance. The reasoning is that they invest a significant amount of money and conduct hundreds to thousands of clinical trials in order to develop an effective medicine; hence, they perceive reliance on their data to obtain marketing approval as a form of unjust free-riding on their efforts.[1] However, the generic manufacturers argue that skipping clinical experimentation leads to widespread and affordable access to medicine in a short span of time. In addition, this process avoids duplicate clinical trials on humans and animals, which in turn successfully evades the unethical concern.[2] An attempt to settle this debate was made in 1994 through a World Trade Organization (hereinafter "WTO") Agreement.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS")[3] is the first international agreement that obliges the Member States to provide a minimum level of protection for the test data submitted by the originator companies for the marketing authorization of their pharmaceutical and agricultural products.[4] While TRIPS Agreement mandates protection of pharmaceutical test data under Article 39.3, its ambiguous language—particularly the undefined scope of "unfair commercial use" and permissible exceptions—has left WTO Member States grappling with reconciling Intellectual Property (hereinafter "IP") obligations with urgent public health needs. This article argues that a pandemic (for instance, the recent COVID-19 pandemic) constitutes an "emergency in international relations" under TRIPS Article 73(b)(iii), providing a legal pathway for states to temporarily suspend test data protection to expedite generic production of essential medicines.

Pharmaceutical test data—the results of clinical trial submitted by originator companies to regulatory agencies for market approval—serves as a gatekeeper for generic competition. By shielding these data from reliance by competitors, test data protection regimes extend monopolies beyond patent (an intellectual property right that is granted to an inventor) protection, delaying affordable generics.[5] During a pandemic, this barrier became

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[1] Peter K. Yu, *Data Exclusivities and the Limits to TRIPS Harmonization*, 46(3) FLA. ST. U. L. REV. 641, 652 (2019).

[2] Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement*, 45(2) HARV. INT'L L.J. 443, 474 (2004).

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

[4] *Id.* art. 39.3.

[5] Médecins Sans Frontières, *Data Exclusivity in International Trade Agreements: What Consequences for Access to Medicines?*, MSF ACCESS (May 27, 2004), https://msfaccess.org/data-exclusivity-international-trade-agreements-what-consequences-access-medicines.

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starkly visible. For instance, while patents for drugs like remdesivir could be circumvented via compulsory licensing, test data exclusivity in jurisdictions like the European Union (hereinafter "EU") and the United States (hereinafter "U.S.") prolonged monopolies, limiting global access.[6] Such delays underscore a systemic flaw in TRIPS. While Article 39.3 obligates states to protect test data, it fails to clarify how members may balance these obligations against public health imperatives during crises.

Existing scholarship has predominantly focused on two axes of debate. First, legal interpretations of Article 39.3's "unfair commercial use" clause, with developed nations advocating for data exclusivity (Correa, 2020)[7] and developing countries favoring cost-sharing or misappropriation models (Reichman, 2009).[8] Second, the role of TRIPS flexibilities like compulsory licensing for patents along with test data protection (Hoen and others, 2017).[9] However, scant attention has been paid to the intersection of test data protection and national security exceptions under Article 73(b)(iii), despite its potential to resolve pandemic-era access barriers. This gap is critical: as the WTO Panel in *Saudi Arabia — Intellectual Property Rights* (hereinafter "IPRs") (2020) affirmed, states may override TRIPS obligations during emergencies threatening "essential security interests"—a precedent this article applies to pandemics.

This study addresses three research questions. Firstly, it seeks to answer the inevitable question- 1) what are the international obligations of a country to protect test data under the TRIPS Agreement? After finding the international obligations of a Member country related to the protection of test data, this paper looks for the available exceptions in this regard and answers the second research question- 2) what are the limits and exceptions to the protection of test data? After getting a comprehensive idea of the international obligations of test data protection and its limits and exceptions, this paper finally looks for the available means to ensure 'access to medicine' by interpreting the provisions of test data protection in the context of the recent COVID-19 pandemic through the research question- 3) how can a country introduce "access to medicine" measures after circumventing the obligation to protect test data amid a pandemic situation?

The analysis of the article proceeds in two parts. First part (Section II) examines the legal contours of Article 39.3, arguing that its deliberate

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[6] CARLOS MARÍA CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 365 (2d ed. 2020).

[7] *Id.*

[8] Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13(1) MARQ. INTELL. PROP. L. REV. 1, 32 (2009).

[9] Ellen F. M. 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10(1) J. PHARM. POL'Y & PRAC. 1, 6 (2017).

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ambiguity grants states flexibility to define "unfair commercial use" in public health contexts. Second part (Section III) evaluates TRIPS exceptions, with a novel focus on Article 73(b)(iii)'s national security clause, drawing parallels between the COVID-19 crisis and the WTO Panel's criteria in the cases *Russia — Measures Concerning Traffic in Transit* (2019) (hereinafter "*Russia — Traffic in Transit*")[10] and *Saudi Arabia — IPRs* (2020).[11] In addition, it proposes a framework for invoking Article 73(b)(iii) during pandemics, balancing IP protections with equitable access.

By reframing pandemics as threats to "essential security interests," this article contributes a timely legal pathway for governments to reconcile IP obligations with the moral imperative of health equity—a tension amplified by COVID-19 and destined to recur in future crises. The following table summarizes key gaps in the existing scholarship on TRIPS flexibilities and outlines this article's contributions. Studies on Article 39.3 often focus narrowly on its internal flexibilities, overlooking how it connects with broader mechanisms such as compulsory licensing and the national security exception under Article 73(b)(iii). Likewise, analyses of data exclusivity models rarely propose pandemic-specific solutions that balance innovation incentives with urgent access needs. This article addresses these gaps by suggesting temporally limited suspensions of exclusivity during health crises, supported by cost-sharing arrangements between originator and generic firms. Finally, while discussions of national security exceptions have largely remained geopolitical, this study extends their relevance to public health by reframing pandemics as "emergencies in international relations."

[10] Panel Report, *Russia — Measures Concerning Traffic in Transit*, WTO Doc. WT/DS512/R (adopted Apr. 26, 2019) [hereinafter *Russia — Traffic in Transit* Panel Report].
[11] Panel Report, *Saudi Arabia — Measures Concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS567/R (adopted June 16, 2020) [hereinafter *Saudi Arabia — IPRs* Panel Report].

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TABLE 1: Synthesis of Gaps and This Article's Contribution

Scholarly Focus	Key Limitations	This Article's Contribution
Article 39.3 interpretations	Overemphasis on flexibilities of TRIPS	Links test data to exceptions of Article 39.3, compulsory licensing and national security exceptions (Article 73(b)(iii))
Data exclusivity models	Neglect of pandemic-specific multiple solutions	Proposes temporally limited suspensions during crises by cost-sharing (Generic firms compensate originators for data use) and mandatory disclosure for public interest
National security exceptions	Geopolitical focus, no health applications (only in few)	Reframes pandemics as "emergencies in international relations"

By bridging these gaps, this article provides a cohesive framework to reconcile test data protection with equitable access—a pressing need in an era of recurring pandemics.

II. INTERNATIONAL OBLIGATIONS OF TEST DATA PROTECTION

Test data protection for submitted data to governments by the originator (first entrant) is a contentious issue of intellectual property. The need for the protection of test data arises when national regulatory authorities require these data from companies for the marketing authorization of medicinal products. The role of the governmental agencies is to assess the safety and efficacy of the products and in order to do so, test data collected through clinical experimentation is required.[12] Given that this concerns the safety and efficacy of the drug, there is a public interest in at least knowing the outcome.[13] For example, access to clinical trials data on COVID-19 vaccines and treatments may assist the scientists and researchers to get a clear idea of

[12] Wael Armouti & Mohammad F.A. Nsour, *Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the US-Jordan Free Trade Agreement?*, 17(2) OR. REV. INT'L L. 259, 263 (2016).

[13] Allison Durkin et al., *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23(1) HEALTH & HUM. RTS. 129, 131 (2021).

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COVID-19 infection and immune responses.[14] On the other hand, given the investment, time, and other difficulties faced by the originator companies to collect test data, they require some sort of protection for those data. Considering the efforts of the innovator as well as the interest of the public, the government has an obligation to ensure the protection of those data only "against disclosure" or "against unfair commercial advantage" but this obligation is subject to some limitations and exceptions which include "public interest."[15]

This article specifically seeks to extrapolate how a country can introduce "access to medicine" measures in public health crises like the COVID-19 pandemic, while aligning with its related obligation to protect test data. Section II of the article proceeds in two sub-sections. While section A identifies the obligations of a WTO Member to protect test data under the TRIPS Agreement, section B analyses the scope of test data protection.

A. Test Data Protection Under the TRIPS Agreement

Test data protection was recognized as a priority at the international level, in the TRIPS Agreement. TRIPS is the first international agreement to introduce an international standard of test data protection. The Agreement, under Part II of Section 7 (the undisclosed information section), which solely includes Article 39, specifically addresses the "Protection of Undisclosed Information".

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

[14] Christopher J. Morten et al., *To Help Develop the Safest, Most Effective Coronavirus Tests, Treatments, and Vaccines, Ensure Public Access to Clinical Research Data*, HEALTH AFFS. (Mar. 26, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20200326.869114/full/.

[15] Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38(1) AM. J. L. & MED. 63, 81 (2012).

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> or unless steps are taken to ensure that the data are protected against unfair commercial use.[16]

A thorough reading of the provision depicts that Article 39.3 provides for test data protection against "unfair commercial use" and "disclosure." While the first sentence of Article 39.3 gives emphasis on the "obligation to protect against unfair commercial use," the second sentence emphasizes the "obligation to protect against the disclosure" of undisclosed test or other data. As such, Article 39.3 established a minimum standard of protection without mandating a comprehensive realm of test data protection.

To a great degree, the sensibly drafted language in Article 39.3 reflects the complex and balanced understanding reached between the developed and developing countries. Typically, developed countries and their R&D-based pharmaceutical industries seek higher protection by regarding the minimum standard of Article 39.3 as a starting point. Accordingly, they frequently are entering into bilateral or regional agreements with the developing countries that include more specific models of test data protection, such as providing an exclusivity period for test data.[17] These agreements (here commonly referred to as Free Trade Agreements (hereinafter "FTAs")) often contain various stringent IP protection provisions which have been highly criticized for limiting widespread and affordable access to medicine for all.[18]

FTAs, both bilateral and regional, have thus become a key instrument for expanding the scope of test data protection beyond the TRIPS framework. The Dominican Republic–Central America FTA (CAFTA–DR), for instance, introduced a five-year data exclusivity period that delayed the market entry of generic medicines in several member states.[19] Similarly, the U.S.–Jordan FTA postponed the introduction of generics for nearly 79 percent of the medicines studied, thereby substantially increasing public health expenditure and limiting access to affordable treatments.[20] The U.S.–Peru FTA further demonstrated the binding nature of these commitments, as Peru was required to implement data exclusivity provisions even several years after ratification.[21] Collectively, these agreements illustrate how test data protection, once conceived under TRIPS as a limited safeguard against

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[16] TRIPS Agreement, *supra* note 3, art. 39.3.
[17] Henning Grosse Ruse-Khan et al., *Principles for Intellectual Property Provisions in Bilateral and Regional Agreements*, 44(8) IIC—INT'L REV. INTELL. PROP. & COMPETITION L. 878, 879 (2013).
[18] Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines—Coming to Grips with TRIPS: Conversion + Calculation*, 38(3) J. L. MED. & ETHICS 520, 532 (2010).
[19] Médecins Sans Frontières, *supra* note 5.
[20] Rohit Malpani, *All Costs, No Benefits: How the US-Jordan Free Trade Agreement Affects Access to Medicines*, 6(3) J. GENERIC MED. 206, 206-17 (2009).
[21] *See generally* Michael Palmedo, *Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports* (Glob. Dev. Pol'y Ctr., Pardee Sch. of Glob. Stud., Boston Univ., GEGI Working Papers No. 48, Apr. 2021), https://www.bu.edu/gdp/files/2021/04/GEGI_WP_048_Palmedo_FIN.pdf.

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unfair competition, has evolved into a powerful exclusivity mechanism under international trade law. This evolution highlights the growing intersection between intellectual property protection and trade liberalization, where TRIPS-plus obligations have progressively constrained the policy space of developing countries to ensure equitable and affordable access to medicines.

Essentially, Article 39.3 mandates test data protection and encapsulates the conditions to be satisfied by the test data to qualify for the "protection against unfair commercial use and disclosure." Those conditions or requirements are:

1. The data must be submitted for marketing approval (submission requirement)
2. The data must relate to a product that contains "new chemical entities" (newness requirement)
3. The data must be "undisclosed" (undisclosed requirement)
4. The generation of the data involves "considerable effort" (effort requirement)

Pursuant to Article 1.1 of TRIPS Agreement, WTO Members can (but do not have to) protect test data under less rigid conditions.[22] Therefore, the WTO Members have sufficient policy space when they interpret the requirements for the protection of test data.[23] For instance, Members are obliged to ensure the protection of test data only when they require them for marketing approval. Moreover, Members can determine the bar in evaluating the "considerable efforts" in light of the relevant domestic circumstances. In this context, Members can collectively or independently consider the significance of (difficulty, costs, and investments) efforts involved in obtaining test data.

B. Scope of Test Data Protection

In essence, Article 39.3 requires two distinct but connected obligations: first, "protection of data against unfair commercial use" and second, "protection of data against disclosure unless it is necessary to protect the public or unless steps are taken to protect against unfair commercial use." Hence, WTO Members must adequately protect eligible "undisclosed test or other data" against "unfair commercial use" and "disclosure." In reference to the non-disclosure obligation, two exceptions are envisaged: one, "when disclosure is necessary to protect the public," and the other "when steps are

[22] TRIPS Agreement, *supra* note 3, art. 1.1 (it states that "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by the TRIPS Agreement, provided that such additional protection does not contravene other provisions of the Agreement").

[23] JUSTIN MALBON ET AL., THE WTO AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 585 (2014).

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taken to ensure that the data will not be used in a commercially unfair manner." While the obligation for protection against disclosure by the health authorities is relatively straightforward, the requirement to protect against "unfair commercial use" is opaque. The analysis of protection against unfair commercial use is, therefore, significant to define the scope of obligation for such protection.

1. Protection Against Unfair Commercial Use — Article 39.3 mandates WTO Member governments to ensure that submitted test data is safeguarded against "unfair commercial use." However, the TRIPS Agreement does not explicitly define this term. Logically, the concept of "unfair commercial use" aligns closely with the meaning of "undisclosed information" as outlined in the preceding section. Consequently, a thorough interpretation of "unfair commercial use" is necessary to determine the precise scope of the obligation in Article 39.3.

The phrase "unfair commercial use" consists of three key elements: "unfair," "commercial," and "use." Applying the interpretative guidance from Articles 31 and 32 of the Vienna Convention on the Law of Treaties (hereinafter "VCLT")[24], each term warrants detailed analysis. The word "unfair" generally signifies a lack of equity, partiality, or deviation from established rules.[25] However, fairness is a relative concept, varying across societies. The interpretation of fairness in this context can be interpreted by taking into account Article 10*bis* of the Paris Convention,[26] which describes unfair competition as any act contrary to honest practices in industrial or commercial matters.[27] The WTO panel in the *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* (hereinafter "*Australia — Plain Packaging*") case[28] elaborated on this by stating that unfair competition involves conduct that deviates from truthful, fair, and non-deceptive market practices.[29] Therefore, a balance is required between the financial interests of the medicine manufacturer and the interests of the public.

From an economic standpoint, the use of the test data will be regarded as commercially unfair when the competitors (the second registrants) receive

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[24] Vienna Convention on the Law of Treaties arts. 31-32 May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT].

[25] *Unfair*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/unfair (last visited Feb. 24, 2024).

[26] Paris Convention for the Protection of Industrial Property art. 10*bis* (2), Mar. 20, 1883, as revised at Stockholm July 14, 1967, and amended 1979, 828 U.N.T.S. 306.

[27] CORREA, *supra* note 6, at 365.

[28] Panel Report, *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/R (adopted June 29, 2020) [hereinafter *Australia — Plain Packaging (Honduras)* Panel Report].

[29] ANTONY TAUBMAN ET AL., A HANDBOOK ON THE WTO TRIPS AGREEMENT 144 (2d ed. 2020).

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an economic advantage from the use of test data submitted by the originator (the first registrant) and the originator is not compensated in any way.[30] While WTO Members may adopt various measures to protect the financial interests of originators, the *Australia — Plain Packaging* panel emphasized that the concept of fairness is relative to the national approaches to fairness or honest practices.[31] The term "commercial" pertains to activities involving commerce or financial gain.[32] Governmental actions, typically administrative rather than commercial, are generally not considered "commercial" in this context. Correa supports this view, arguing that government reliance on test data for regulatory approval does not constitute a commercial activity but rather a legitimate sovereign function.[33]

Not all third-party uses of test data trigger the obligation to protect against "unfair commercial use." For instance, national regulatory agencies assessing medicinal product efficacy and safety do not engage in commercial use, as they lack direct financial interest. The WTO panel's findings in *China — IPRs* clarify that "commercial scale" refers to the magnitude of economic activity rather than all forms of commercial conduct.[34] However, an objection was raised regarding the conduct of the regulatory bodies to rely on the test data to authorize competing products.[35] Consequently, the objection was overshadowed by the argument that data reliance is a legitimate sovereign practice rather than a commercial activity.[36] Moreover, the commercial use is made by somebody who is actually in commerce. Therefore, the commercial characterization does not go with the activities of the national health regulatory agencies.

The term "use" denotes the act of employing data for a specific purpose.[37] Within Article 39.3 of TRIPS Agreement, various forms of test data utilization exist: (i) regulatory agencies using test data to assess the safety and efficacy of the originator's product, (ii) independent researchers analyzing test data for scientific evaluation, (iii) third parties illicitly acquiring test data, and (iv) regulatory agencies relying on test data for approving bioequivalent generic products. The fourth type, known as

[30] Fellmeth, *supra* note 2, at 464.
[31] *Australia — Plain Packaging*, *supra* note 28, ¶ 7.2682.
[32] *Commercial*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/commercial (last visited Feb. 24, 2024).
[33] Carlos María Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for Registration of Pharmaceuticals*, 3(1) CHI. J. INT'L L. 69, 78 (2002).
[34] Daniel Gervais, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, 103(3) AM. J. INT'L L. 549, 552 (2009).
[35] Ingo Meitinger, *Implementation of Test Data Protection According to Article 39.3 TRIPS: The Search for a Fair Interpretation of the Term "Unfair Commercial Use"*, 8(2) J. WORLD INTELL. PROP. 123, 131 (2005).
[36] Biswajit Dhar & K.M. Gopakumar, *Data Exclusivity in Pharmaceuticals: Little Basis, False Claims*, 41(49) ECON. & POL. WKLY. 5,073, 5,075 (2006).
[37] *Use*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/use (last visited Feb. 13, 2023).

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"regulatory reliance," aims to prevent redundant testing and facilitate affordable access to medicines.

There is scholarly debate over whether indirect regulatory reliance constitutes "use" under TRIPS Agreement. Some argue that reliance on test data to approve bioequivalent generics does not constitute "unfair commercial use."[38] The Canadian case of *Bayer Inc. v. Canada (Attorney General)* [39] supports this stance, as the court ruled that reliance on bioequivalence data did not amount to unfair commercial use. Others contend that even indirect reliance confers a commercial advantage to generic manufacturers, thereby constituting unfair use.[40] The economic impact perspective[41] suggests that regulatory reliance deprives originators of opportunities to recoup investments in test data, which may be interpreted as an unfair practice under Article 39.3.

The interpretation of "unfair commercial use" can also be analyzed under Article 32 VCLT, which allows for supplementary means of interpretation in cases of ambiguity.[42] The TRIPS negotiation history reveals that early drafts sought to classify governmental reliance on test data as commercial use.[43] However, this was ultimately rejected.[44] The U.S., Switzerland, and the European Community (hereinafter "EC") proposed alternative definitions, with the latter suggesting protection against "unfair exploitation" rather than governmental use.[45] The final TRIPS text retained "unfair commercial use" without explicitly prohibiting reliance practices by national regulators.

The WTO Appellate Body ruling in the *India Mailbox* Case[46] further underscores that WTO panels cannot add to or subtract from existing TRIPS obligations.[47] Since TRIPS Agreement allows Members to determine their

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[38] CORREA, *supra* note 6, at 368.
[39] *Bayer Inc. v. Canada (Attorney General)*, 87 C.P.R. (3d) 293 (Can. Fed. Ct. 1999).
[40] Correa, *supra* note 33, at 80.
[41] *See* G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24(1) NW. J. INT'L L. & BUS. 1, 30 (2003).
[42] VCLT, *supra* note 24, art. 32.
[43] Jerome H. Reichman, *Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective*, *in* UNCTAD-ICTSD DIALOGUE ON MOVING THE PRO-DEVELOPMENT IP AGENDA FORWARD: PRESERVING PUBLIC GOODS IN HEALTH, EDUCATION AND LEARNING 1, 10 (2004).
[44] *See generally* General Agreement on Tariffs and Trade, *Suggestion by the United States for Achieving the Negotiating Objective*, GATT Doc. MTN.GNG/NG11/W/14 (Oct. 20, 1987), https://www.wto.org/gatt_docs/English/SULPDF/92030039.pdf.
[45] *See generally* General Agreement on Tariffs and Trade, *Draft Agreement on Trade-Related Aspects of Intellectual Property Rights*, GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990), https://www.wto.org/gatt_docs/English/SULPDF/92100042.pdf.
[46] Appellate Body Report, *India — Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 47, WTO Doc. WT/DS50/AB/R (adopted Jan. 16, 1998).
[47] Understanding on Rules and Procedures Governing the Settlement of Disputes art. 19, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

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implementation methods, the interpretation of "unfair commercial use" remains flexible.[48] However, it generally aligns with the notion of "unjust exploitation" of test data for commercial gain. The deliberate ambiguity in Article 39.3 indicates that WTO Members have discretion in structuring test data protection measures, provided they prevent all forms of "unfair commercial use."

2. Protection Against Disclosure — In conjunction with the obligation to protect test data against "unfair commercial use," Article 39.3 mandates WTO Members to protect test data against "disclosure." This non-disclosure obligation typically means that governments and health regulatory agencies of Members are prevented from communicating the test data to any third party, i.e., generic competitors of the originator of test data.[49] Implicitly, it also means that governmental authorities of Members have to take sufficient measures to prevent leakage of the pertinent test data.[50] However, this non-disclosure obligation is subject to two exceptions: one "when disclosure is necessary to protect the public" and the other "when steps are taken to ensure that the data are protected against unfair commercial use."[51] These two exceptions will be discussed in detail in the next part of the paper.

III. TEST DATA PROTECTION: EXCEPTIONS AND LIMITATIONS

Considering the recent COVID-19 pandemic situation, a hypothetical situation may arise when a new treatment for COVID-19 on basis of e.g. Remdesvir and Kaletra would constitute a new medical use with a new active substance, and if this were the case, also a new application with new clinical and pre-clinical trials to prove quality, safety and efficacy will be necessary to obtain marketing approval.[52] In this context, Members can protect the test data under the test data protection regime. Here it will be interesting to see whether exceptions can take place to circumvent this obligation for the protection of test data.

There are several provisions in TRIPS that deal with the protection of public interest as well as the interests of the developing and least-developed countries (hereinafter "LDCs"). Those provisions are commonly referred to as TRIPS flexibilities. One of the flexibilities is stated in Article 7 of the TRIPS Agreement which provides the Members policy space to implement the Agreement by balancing the objectives and promoting socio-economic

[48] TRIPS Agreement, *supra* note 3, art. 1.1.
[49] Gabriele Spina Alì, *TRIPS and Disclosure of Clinical Information: An Intellectual Property Perspective on Data Sharing*, 20(1-2) J. WORLD INTELL. PROP. 24, 33 (2017).
[50] *Id*.
[51] TRIPS Agreement, *supra* note 3, art. 39.3.
[52] Dhanay Cadillo Chandler, *Uh-Oh We Are in Trouble! Compulsory Licences v. Data Exclusivity in the EU: One More Challenge to Overcome in the Race to Find a COVID-19 Vaccine?*, 42(9) EUR. INTELL. PROP. REV. 539, 543 (2020).

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welfare.[53] In a similar vein, Article 8.1 depicts the principle of "public interest" and permits Members to take necessary measures to protect public health.[54] In sum, TRIPS Articles 7 and 8 pay regard to the development dimension of countries to protect public health and interest.[55] This position is further strengthened by the provision of Article 39.3 as it allows an exception when it is necessary to protect public health.

A. Specific Exceptions and Limitations Under Article 39.3

As stated earlier, in addition to the obligation to protect test data "against unfair commercial use", Article 39.3 also mandates the Members to protect data against "disclosure". The concluding part of Article 39.3 specifically provides two exceptions to this non-disclosure obligation. In other words, although the TRIPS provision imposed an obligation, the Members can disclose the data if permitted by the exceptions.

1. Allowance for Disclosure in Cases "Necessary to Protect the Public" — Disclosure of test data is permitted when it is necessary to protect the public, i.e., public interests. The rationale behind this is to avoid "damage to humans, animals or the environment by wrongful use of a product or to inform about discovered deficiencies of a product".[56] Disclosure of test data, by permitting scientists or researchers to review the data, may assist to reveal the potential side effects of a drug.[57] For example, an independent review of test data by researchers from the Cochrane group discovered the inefficacy of "Tamiflu" to treat the bird flu.[58] Therefore, it seems that the information relating to test data can be disclosed not only for the community as a whole but also for the benefit of a group of people sharing a common interest. In addition, since Article 39.3 has not mentioned the specific interest for disclosure, the relevant data may be disclosed for the protection of a broad

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[53] Henning Grosse Ruse-Khan, *The Principle of Integration in WTO/TRIPS Jurisprudence*, *in* SUSTAINABLE DEVELOPMENT PRINCIPLES IN THE DECISIONS OF INTERNATIONAL COURTS AND TRIBUNALS 398, 406 (Marie-Claire Cordonier Segger & C.G. Weeramantry eds., 2017).

[54] Henning Grosse Ruse-Khan, *Policy Space for Domestic Public Interest Measures Under TRIPS*, 22 S. CTR. RSCH. PAPER 1, 15 (2009).

[55] Olasupo Ayodeji Owoeye, *Patents and the Obligation to Protect Health: Examining the Significance of Human Rights Considerations in the Protection of Pharmaceutical Patents*, 21(4) J. L. & MED. 900, 915-16 (2014).

[56] *See generally* Ingo Meitinger & Mira Burri, *Protection of Undisclosed Information: Commentary of Article 39 TRIPS*, *in* CONCISE INTERNATIONAL AND EUROPEAN IP LAW: TRIPS, PARIS CONVENTION, EUROPEAN ENFORCEMENT AND TRANSFER OF TECHNOLOGY 131 (Thomas Cottier & Pierre Véron eds., 2014).

[57] Nikolaos Evangelatos et al., *Clinical Trial Data as Public Goods: Fair Trade and the Virtual Knowledge Bank as a Solution to the Free Rider Problem—A Framework for the Promotion of Innovation by Facilitation of Clinical Trial Data Sharing Among Biopharmaceutical Companies in the Era of Omics and Big Data*, 19(4) PUB. HEALTH GENOMICS 211, 213 (2016).

[58] Pamela Andanda, *Managing Intellectual Property Rights over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health*, 44(2) IIC—INT'L REV. INTELL. PROP. & COMPETITION L. 140, 152 (2013).

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spectrum of public grounds.[59] Hence, the ground for disclosure is not necessary to be related to human health and the exception may be invoked in case of disclosure which is essential for public protection. So, in case of a modest contribution, disclosure cannot be made. It is important to note here that this necessity criterion, stated in the first exception to the non-disclosure obligation, is tantamount to the provision of "Article XX of the General Agreement on Tariffs and Trade (hereinafter "GATT")."[60]

Consequentially, this exception is subject to a necessity test under WTO's rules.[61] According to WTO's jurisprudence, data disclosure will be regarded as "necessary" to protect the public only if a similar kind of protection cannot be achieved through reasonable alternative measures.[62] The reason could be either the alternatives are ineffective, or they will create an unreasonable burden to the invoker of exceptions. In this regard, some notable WTO cases within the context of GATT can shed some light but it is to be remembered that the Panel or Appellate Body may not construe the concept of necessity the same way when interacting with it within the TRIPS context. However, those cases can facilitate construing the concept of necessity.

In *United States — Imports of Certain Automotive Spring Assemblies* (hereinafter "*US — Spring Assemblies*"),[63] the notion of necessity was defined on the basis of whether a satisfactory and effective alternative existed. However, the Panel in *Thailand — Restrictions on Importation of and Internal Taxes on Cigarettes* (hereinafter "*Thailand — Cigarettes*") ruled that Thailand's import ban on cigarettes was justified under Article XX(b):

> The Panel noted that this provision clearly allowed contracting parties to give priority to human health over trade liberalization; however, for a measure to be covered by Article XX(b) it had to be "necessary" . . . The Panel concluded . . . that the import restrictions imposed by Thailand could be considered to be "necessary" in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives.[64]

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[59] Spina Alì, *supra* note 49, at 34.
[60] General Agreement on Tariffs and Trade [hereinafter GATT], art. XX, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194; *see also* Fellmeth, *supra* note 2, at 450-52.
[61] CORREA, *supra* note 6, at 364.
[62] Lemmens & Telfer, *supra* note 15, at 87.
[63] Report of the Panel, *United States — Imports of Certain Automotive Spring Assemblies*, ¶ 58, L/5333 (June 11, 1982), GATT B.I.S.D. (30th Supp.), at 107 (1983).
[64] Report of the Panel, *Thailand — Restrictions on Importation of and Internal Taxes on Cigarettes*, ¶¶ 73, 75, DS10/R (Oct. 5, 1990), GATT B.I.S.D. (37th Supp.), at 200 (1990).

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Later, in *European Communities — Measures Affecting Asbestos and Products Containing Asbestos* (hereinafter "*EC — Asbestos*"), the Appellate Body concluded that "the . . . question . . . is whether there is an alternative measure that would achieve the same end and that is less restrictive of trade than a prohibition."[65] Therefore, the WTO case laws suggest that deference is provided to WTO Members to ascertain when the necessity arises, but the invoking Member has to bear the onerous burden of proof.[66] In this context, scholar Arrivilaga has opined that the Doha Declaration can provide guidance to determine measures that are "necessary to protect the public."[67] Therefore, it can be logically deduced that the disclosure will be regarded as "necessary" when it is required to allow the public to make informed therapeutic decisions to protect their right to health. In summary, test data can be divulged in cases necessary for public protection either to a state-run company or a generic pharma company under the confidentiality agreement following the cost-sharing approach (licensing fees or some form of payment). In all cases, precautions should be taken to avoid commercial detriments to the originator company.

2. Alternatively, Allowance for Disclosure as Long as Protection Against Unfair Commercial Use Is Provided — Disclosure of test data is permitted if sufficient steps are taken to protect data "against unfair commercial use". This second exception to the non-disclosure obligation permits Members to divulge the pertinent information if there are reasonable measures in place for the protection of test data "against unfair commercial use."

The second sentence of Article 39.3 begins with the phrase "In addition . . ." which suggests that the non-disclosure obligation is a supplementary obligation to the primary obligation "to protect test data against unfair commercial use".[68] It also implies that the condition of disclosure prohibition is cumulative in the sense that both the protection against "unfair commercial use" and "disclosure" are mandated by Article 39.3.[69] Even now, the second exception to the "protection against disclosure" seems to allow Members to disclose test data if sufficient steps are taken to protect data against unfair commercial use.

The exact meaning of the permission to disclose test data—the second exception to the disclosure—is to be understood as requiring an enhanced

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[65] Appellate Body Report, *European Communities—Measures Affecting Asbestos and Products Containing Asbestos*, ¶ 172, WTO Doc. WT/DS135/AB/R (adopted Apr. 5, 2001).
[66] MICHAEL J. TREBILCOCK & ROBERT HOWSE, THE REGULATION OF INTERNATIONAL TRADE 140 (2d ed. 1999).
[67] Lucas R. Arrivillaga, *An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs: TRIPS Article 39.3*, 6(1) J. WORLD INTELL. PROP. 139, 150 (2003).
[68] NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENTS AND TEST DATA 583 (5th ed. 2017).
[69] Skillington & Solovy, *supra* note 41, at 48.

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level of protection by the governmental agencies of Members before disclosing the data. This heightened level of protection is relative to the level of the primary obligation mandated by the introductory sentence of Article 39.3. In essence, despite mentioning the obligation stated in the introductory sentence that Members "shall protect such data against unfair commercial use," the last sentence states that "steps are taken to ensure that the data are protected against unfair commercial use." The interpretation of this clause hinges on the legal weight of the verb "*ensure*." Under the VCLT**,** treaty terms must be interpreted in good faith according to their ordinary meaning**,** context, and object and purpose (Article 31). A textual analysis of Article 39.3 reveals a deliberate shift in terminology. The first sentence requires Members to "protect" test data, which constitutes a general duty implying that laws or administrative measures must be in place. The second sentence, however, permits disclosure only if steps are taken to "ensure" protection. The ordinary meaning of "ensure," which is to "make certain or guarantee that something occurs", imposes an obligation to achieve a result, not merely a procedural one. This requires Members to guarantee that data remain effectively protected even after disclosure, reflecting a heightened and enhanced level of protection.[70] This interpretation is reinforced by the object and purpose of Article 39.3, which seeks to balance the interests of innovators in protecting valuable data against the public interest in accessing information. Because disclosure represents a significant concession to the public interest, it must be offset by a stronger legal assurance for the data submitters. Therefore, the phrase "sufficient steps are taken to ensure" must entail substantive guarantees, such as compensatory mechanisms or defined periods of continued exclusive protection, rather than mere procedural safeguards. While calculating the period of protection, under TRIPS Article 1.1, Members have the freedom to set their own rules to determine the length of the term of protection.[71] However, an ordinary level of protection for test data may suffice if the data are not disclosed.

B. Test Data Protection and Compulsory Licensing: Does the Test Data Protection Interfere with the Ability to Grant a Compulsory License?

Compulsory licensing is a mechanism under which a government can grant itself or any third party the right to use patented inventions without the authorization of the patent owner. Under TRIPS, the compulsory licensing mechanism is considered to be a flexibility which can be found in Article 31 under the heading of "other use without authorization of the right holder."

[70] Spina Alì, *supra* note 49, at 36.
[71] CARVALHO, *supra* note 68, at 588.

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The Doha Declaration also reaffirmed this use by acknowledging the public health concerns.[72] However, TRIPS requires that this use is subject to the payment of "adequate" remuneration to the right holder.[73]

For illustrative purposes in the context of future pandemics, a situation may arise when the government issues a compulsory license in favour of a generic company to produce vaccines or repurposed drugs without the consent of the patent holder. In that case, the test data protection chapter may create an additional barrier as the relationship between compulsory licensing and test data protection is intrinsically complicated. Typically, compulsory licensing is an exception to patent rights, but not to test data protection. In fact, Article 39.3 has not mentioned anything related to the compulsory licensing of test data protection. However, Article 7 (balance between objectives), Article 8.1 (principles of public interest), and para. 4 of the Doha Declaration suggest that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."[74] Based on the interpretation of these provisions, one can argue that compulsory licensing of test data protection is possible in order to protect public health.[75]

A more powerful and textually grounded argument arises from a structural analysis of the TRIPS Agreement itself, applying the interpretive canon of *expressio unius est exclusio alterius* (the express mention of one thing excludes others). The drafters of the Agreement knew how to prohibit compulsory licensing for specific categories of intellectual property when they intended to do so. For example, Article 21 explicitly states that "the compulsory licensing of trademarks shall not be permitted." The absence of any such prohibition in Article 39 for undisclosed information, including test data, is therefore legally significant.[76] This textual silence, when contrasted with the explicit prohibition in Article 21, creates a strong inference that the compulsory licensing of undisclosed information is not forbidden and is a permissible policy option.

This interpretation, according to Hoen and others (2017), would allow test data to be shared concurrently with a compulsory license issued for the patent.[77] Such a mechanism would be crucial in a public health crisis, as it would permit generic versions of a patented drug to be made available to the

[72] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, ¶ 4, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001).
[73] TRIPS Agreement, *supra* note 3, art. 31(h).
[74] David S. Levine, *Covid-19 Trade Secrets and Information Access: An Overview*, INFOJUSTICE (July 10, 2020), http://infojustice.org/archives/42493.
[75] Kung-Chung Liu, *The Need and Justification for a General Competition-Oriented Compulsory Licensing Regime*, 43(6) IIC—INT'L REV. INTELL. PROP. & COMPETITION L. 679, 683 (2012).
[76] Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16(11) J. INTELL. PROP. L. & PRAC. 1,242, 1,251 (2021).
[77] Hoen et al., *supra* note 9, at 6.

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public without undue delay. Therefore, no definitive bar prevents a government from issuing a compulsory license for test data protection.

C. A Necessary Bridge: The Insufficiency of Existing Flexibilities in a Pandemic

While the TRIPS flexibilities discussed above exist in theory, their practical application during a fast-moving global health crisis is severely hampered by legal, procedural, and political obstacles. Proponents of the TRIPS waiver for COVID-19 argued that existing flexibilities were "never designed to address a health crisis of this magnitude."[78] The pandemic revealed that the standard toolkit is fundamentally ill-suited for such exceptional circumstances, necessitating a more powerful and comprehensive legal instrument.

The limitations of existing flexibilities are manifold:

1. Procedural Barriers — The compulsory licensing system under TRIPS is a "burdensome and time-consuming process" and ill-suited for a rapid pandemic response.[79] For countries without sufficient domestic manufacturing, the mechanism is even more complex, requiring both the importing and exporting countries to issue "parallel compulsory licenses" under the cumbersome Article 31*bis* system. This system also requires the importing nation to prove "insufficient manufacturing capacity"—a term lacking clear criteria under TRIPS. The near-total failure of this system is evidenced by the fact that it has only been successfully used once in its history, for a Canadian export of human immunodeficiency virus (hereinafter "HIV")/AIDS drugs to Rwanda.[80] This country-by-country, product-by-product approach is too fragmented and slow to mount the rapid, coordinated global response required to combat a pandemic.

2. Limited Scope — Modern medical technologies, particularly complex biologics and vaccines, face a "dual IP barrier" of patents and trade secrets.[81] A compulsory license under Article 31 is a tool to overcome the patent barrier, but it is often insufficient for production because it does not grant access to the essential manufacturing know-how, which is protected as

[78] Bryan Mercurio & Pratyush Nath Upreti, *From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments*, 21(5) WORLD TRADE REV. 633, 635 (2022).

[79] Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic* 26 (London Sch. Econ. & Pol. Sci., Working Paper No. 06, 2021).

[80] Jillian Kohler et al., *Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse Among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders*, 24(2) HEALTH & HUM. RTS. 159, 166 (2022).

[81] WooJung Jon, *The WHO Pandemic Agreement: Why Countries Will Not Use Compulsory Licensing – and How to Fix It*, 10(9) BMJ GLOB. HEALTH 1, 1 (2025).

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undisclosed information (trade secrets).[82] Unlike patents, trade secrets are by definition undisclosed, and companies often deliberately omit key manufacturing processes from patent applications to maintain a competitive advantage. For complex biologics, a patent license without the associated know-how is often useless, rendering the compulsory license an "empty gesture".

3. Political and Economic Pressure — Developing countries have been "systematically discouraged" from using TRIPS flexibilities due to immense political and economic pressure from developed countries and pharmaceutical corporations.[83] This pressure takes multiple forms, including the threat of trade sanctions through mechanisms like the U.S. Trade Representative's "Special 301 Report," which has historically targeted countries like Brazil, India, South Africa, and Thailand for using or considering compulsory licenses.[84] The EU has exerted similar pressure. Corporations have also launched direct legal challenges, such as Gilead suing the Russian government for issuing a compulsory license for remdesivir.[85] This coercive environment deters many governments from utilizing flexibilities they are legally entitled to use, particularly during a crisis when they are most vulnerable.

In conclusion, the existing framework of TRIPS flexibilities is inadequate for the scale and urgency of a global pandemic. Their procedural hurdles, limited substantive scope, and susceptibility to political pressure reveal a critical gap in the international legal architecture for public health emergencies. This gap necessitates a turn to a more robust and overarching safeguard that can override all TRIPS obligations simultaneously to protect national and global security. This provides the compelling justification for examining the national security exception under Article 73(b)(iii).

4. Invoking National Security Exceptions Under Article 73(b)(iii): The Ultimate Safeguard — The recent coronavirus (COVID-19) pandemic has led states to contemplate measures to suspend patent laws, test data protection, and other IPRs to facilitate the production and importation of medicines, vaccines, and medical devices. In this regard, some legal scholars and experts have suggested that the recent COVID-19 crisis can be considered an "emergency in international relations" and WTO Members can

[82] *Id.*
[83] Médecins Sans Frontières, *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF BRIEFING DOCUMENTS (May 2021), https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.
[84] *Id.*
[85] *Id.*

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invoke the "national security exception" in Article 73(b)(iii) of the TRIPS Agreement to override IPRs in response to the pandemic.[86]

Article 73 of TRIPS contains a safeguard clause that is equivalent to Article XXI of the GATT[87] and Article XIV*bis* of the General Agreement on Trade in Services (GATS)[88] and it states that "[n]othing in [TRIPS] shall be construed . . . to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests . . . (iii) taken in time of war or other emergency in international relations." Therefore, the text of Article 73(b)(iii) sets out the national security exceptions to TRIPS commitments that the WTO member states can exercise these exceptions to defend their non-compliance with TRIPS. This TRIPS flexibility allows a Member state to suspend its obligations by providing the justification for protecting its essential security interests. This provision is essentially linked with the notion of state sovereignty both in international law and intellectual property law. As Eisenhut posits, "[s]ecurity is at the core of a State's right to exist",[89] adding that "[t]he Hobbesian concept of a State as the protector against threats from inside or outside of its walls is one of the theoretical bases of State sovereignty."[90] He further added that "[a]lthough the idea of unlimited State sovereignty today is no longer undisputed, the pivotal obligation of a State to protect its citizens' security makes the right to do so one of the bedrock features of this concept."[91] Article 73, therefore, reaffirms that Member countries can take steps in pursuance of their sovereign interests even in the context of international intellectual property law. In the words of Grosse Ruse-Khan, "To the extent that these exceptions allow domestic measures to take priority over TRIPS obligations, they amount to *de facto* conflict rules so that their treatment here is justified."[92]

Throughout the history of GATT and WTO, states invoked security exceptions for non-compliance with the substantive obligations in a number of situations. For instance, the U.S. adopted a law prohibiting the export of certain products from the United States to Czechoslovakia which was later disputed by Czechoslovakia. However, the complaint was rejected and the U.S. took the view that its action was justified because "every country must

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[86] *See generally* Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* (FSU Coll. L., Pub. L. Rsch. Paper, Paper No. 9302020, 2020).

[87] GATT, art. XXI, Apr. 15, 1994, Marrakesh Agreement Establishment the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153.

[88] General Agreement on Trade in Services, art. XIV*bis*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, 1869 U.N.T.S. 183, 33 I.L.M. 1167.

[89] Dominik Eisenhut, *Sovereignty, National Security and International Treaty Law: The Standard of Review of International Courts and Tribunals with Regard to "Security Exceptions"*, 48(4) ARCHIV DES VÖLKERRECHTS 431, 431 (2010).

[90] *Id.*

[91] *Id.*

[92] HENNING GROSSE RUSE-KHAN, THE PROTECTION OF INTELLECTUAL PROPERTY IN INTERNATIONAL LAW 409 (2016).

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have the last resort relating to its own security".[93] Even in 1982, the EC, Canada, and Australia imposed trade restrictions on Argentina. During the GATT Council discussions, delegates of the EC, Canada, and Australia stated that "they had taken these measures on the basis of their inherent rights of which Article XXI of the General Agreement was a reflection."[94] Hence, the security exceptions were viewed as "self-judging", and as a result, the precise scope of these exceptions was not clear. Very recently, two WTO panels have shed some light on the interpretation and scope of "national security" exceptions for non-compliance of TRIPS and IPRs, one is the panel in *Russia — Traffic in Transit,*[95] and the other is the panel in *Saudi Arabia — IPRs.*[96] The decisions of both panels explained and interpreted the scope of national security exceptions by addressing the issues of WTO-inconsistent measures. While the panel in the *Russia — Traffic in Transit* case addressed the issues raised under GATT Article XXI(b)(iii), the panel in the *Saudi Arabia- IPRs* case dealt with the situation under TRIPS Article 73(b)(iii). The *Saudi Arabia — IPRs* panel interpreted and analyzed TRIPS Article 73(b)(iii), relying on the jurisprudence of the *Russia — Transit* decision as TRIPS Article 73(b)(iii) mirrors the provision of GATT Article XXI(b)(iii).

In the *Saudi Arabia — IPRs* dispute, a complaint was made by Qatar against Saudi Arabia for the non-application of TRIPS and IPRs. Relying on the security exception in Article 73(b)(iii) of the TRIPS, Saudi Arabia tried to justify its actions and omissions that prevented a Qatari business company, beIN, to obtain legal representation to enforce its IP rights in administrative and civil enforcement procedures before the courts and tribunals of Saudi Arabia. This prevention constituted a violation of Saudi Arabia's obligations under Article 41 of TRIPS. Qatar also claimed that the Saudi government refused to apply criminal procedures against the Saudi Arabian infringer company, beoutQ, which was commercially involved in copyright piracy by streaming copyright-protected contents belonging to beIN. This violated Saudi Arabia's obligations under Article 61 of the TRIPS Agreement. In this regard, the Saudi government contended that its measures were justified because it cut off all relations with Qatar to protect its essential security interests from the dangers of extremism and terrorism.[97]

The Panel in *Saudi Arabia — IPRs,* relying on the jurisprudence of the Panel in *Russia — Traffic in Transit*, presented a consolidated overview of the analytical framework and it listed the following four steps in this regard:

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[93] Michael J. Hahn, *Vital Interests and the Law of GATT: An Analysis of GATT's Security Exception*, 12(3) MICH. J. INT'L L. 558, 570 (1991).
[94] Hannes L. Schloemann & Stefan Ohlhoff, *"Constitutionalization" and Dispute Settlement in the WTO: National Security as an Issue of Competence*, 93(2) AM. J. INT'L L. 424, 436 (1999).
[95] *Russia — Traffic in Transit* Panel Report, *supra* note 10.
[96] *Saudi Arabia — IPRs* Panel Report, *supra* note 11.
[97] *Id.* ¶ 7.258.

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1. whether the existence of a "war or other emergency in international relations" has been established in the sense of subparagraph (iii) to Article 73(b);
2. whether the relevant actions were "taken in time of" that war or other emergency in international relations;
3. whether the invoking member has articulated its relevant "essential security interests" sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and
4. whether the relevant actions are so remote from, or unrelated to, the "emergency in international relations" as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.[98]

Therefore, the first step is that the existence of a "war or other emergency in international relations" has been determined within the meaning of Article 73(b)(iii). Regarding this, the panel in *Russia — Traffic in Transit* opined that the determination of an emergency should be supported by objective facts, and it is not subject to the discretion available to states.[99] Thus, the panel took the view that the security exception is not "self-judging," rather the requirements to invoke exception should be objectively determined.[100] In the context of the phrase "emergency in international relations," the panel remarked that it requires a "situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state."[101] The definition, thereby, suggests a situation akin to an armed conflict. The recent COVID-19 pandemic is plainly not a situation in the context of armed conflict. Nonetheless, the rapid infectious spread of a pandemic and its ever-increasing death toll can affect a country's ability to maintain law and order. The Panel in *Saudi Arabia — IPRs* viewed that the measures taken by Saudi Arabia were for the maintenance of law and order interests which sufficiently establish an "emergency in international relations."[102] The panel pointed out the fact that Saudi Arabia had severed its diplomatic and consular ties with Qatar to protect its security interests from the potential threat of extremism and terrorism. The Panel concluded that "when a group of States repeatedly accuses another of supporting terrorism and extremism, . . . that in and of itself reflects and contributes to a

[98] *Id.* ¶ 7.242.
[99] *Russia — Traffic in Transit* Panel Report, *supra* note 10, ¶¶ 7.71, 7.100.
[100] *Id.* ¶ 7.101.
[101] *Id.* ¶¶ 7.76, 7.111.
[102] *Saudi Arabia — IPRs* Panel Report, *supra* note 11, ¶ 7.257.

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'situation . . . of heightened tension or crisis' between them that relates to their security interests."[103]

The following table provides a comparative overview of Article 73(b)(iii) and existing TRIPS flexibilities to highlight their respective scope and limitations. While compulsory licensing under Article 31 and the Doha Declaration on the TRIPS Agreement and Public Health offer targeted remedies for patent-related barriers, they remain limited in addressing broader forms of intellectual property, such as test data and trade secrets. Moreover, these mechanisms often involve complex procedural requirements and provide only partial relief during public health crises. In contrast, Article 73(b)(iii) operates as a comprehensive safeguard, allowing Member States to suspend all TRIPS obligations when confronting an "emergency in international relations." This provision therefore offers a broader and more immediate legal basis for action, albeit subject to a stringent necessity threshold.

TABLE 2: Comparative Analysis: Article 73(b)(iii) vs. Existing Flexibilities

Mechanism	Advantages	Limitations
Compulsory licensing (Art. 31)	Targets patents directly.	Does not address test data exclusivity.
Doha Declaration	Affirms public health prioritization.	Lacks enforceability for non-patent IP.
Art 73(b)(iii)	Overrides all TRIPS obligations, including data.	Requires high threshold of "emergency."

Regarding the recent COVID-19 outbreak, one could argue that the scale and severity of the threat posed by the pandemic, plus the clarifications under para.5(c) of the Doha Declaration that "public health crises, including . . . epidemics can represent a national emergency," suggest that the recent COVID-19 pandemic could be deemed an "emergency in international relations." This view that pandemic can be referred as international emergency is also supported by the UN Trade and Development (hereinafter "UNCTAD") resource book as it notes: "[a]rguably, pandemics such as HIV

[103] *Id.* ¶ 7.263.

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could be qualified as 'emergencies in international relations' as provided under Article 73(b)(iii) (the international relations component being the failure to obtain adequate supplies of medicines within the framework of the multilateral institutional structure)."[104] In addition, the declaration by WHO, stating a pandemic as a "Public Health Emergency of International Concern (PHEIC)," arguably support an application of Article 73(b)(iii) of TRIPS.

In relation to the second step, i.e. that the relevant measures be taken "in time of war or other international relations," whatever measures a country takes to contain the pandemic are to be taken during the pandemic, including the measures to prevent the re-emergence of the virus. This step, therefore, does not require much discussion.

Concerning the third step, i.e. that the relevant measures taken by the country articulated its "essential security interests," the *Russia — Traffic in Transit* panel distinguishing between "security interests" and "essential security interests" stated that:

> "Essential security interests", which is evidently a narrower concept than "security interests", may generally be understood to refer to those interests relating to the quintessential functions of the state, namely, the protection of its territory and its population from external threats, and the maintenance of law and public order internally.[105]

It can be argued that it is the "quintessential function" of a state to protect the health and safety of its citizens, and a pandemic can affect the ability of the state to maintain the internal public order. The panel in *Saudi Arabia — IPRs* took the view that the actions taken by Saudi Arabia had articulated its "essential security interests" by protecting itself from the dangers of extremism and terrorism.[106] Concerning the recent pandemic outbreak, a particular measure taken by a WTO member, exercising its essential security interests, must do so in accordance with the WTO obligation of good faith[107] to maintain law and public order within its territory as well as maintaining public health i.e. preventing hospitals from overflowing with patients.

With respect to the fourth and final step, i.e. whether "the relevant actions are so remote from, or unrelated to, the 'emergency in international relations' as to make it implausible that the invoking member considers those actions to be necessary,"[108] the *Russia — Traffic in Transit* panel adopted a

[104] UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 805 (2005).
[105] *Russia — Traffic in Transit* Panel Report, *supra* note 10, ¶ 7.130.
[106] *Saudi Arabia — IPRs* Panel Report, *supra* note 11, ¶ 7.280.
[107] *Russia — Traffic in Transit* Panel Report, *supra* note 10, ¶¶ 7.132-38.
[108] *Saudi Arabia — IPRs* Panel Report, *supra* note 11, ¶ 7.242.

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standard based on the minimum requirement of plausibility.[109] The standard suggests that the relevant actions should not be so "remote from, or unrelated to" the "emergency" that it is implausible that the country implemented the measures for the protection of its own "essential security interests arising out of the emergency."[110]

In *Saudi Arabia — IPRs*, the panel held that the plausibility requirement relating to the articulated essential security interests fulfilled in Saudi Arabia's anti-sympathy measures by preventing beIN to receive legal representation to administer its IP rights in civil enforcement procedures. However, the panel observed that there was no plausible relationship between Saudi Arabia's failure to bring criminal proceedings against beoutQ because it affected not only Qatari nationals but also multiple third-party right holders of other countries. Therefore, with regard to the crisis caused by COVID-19 or any pandemic, a country seeking to produce medicines overriding the test data protection and other IP protection invoking the defence of Article 73(b)(iii) would have to show that the relevant implemented measures are not unrelated to or remote from the emergency. Theoretically, now if a WTO member state suspends the protection and enforcement of IP rights to address any future pandemic, it can do so by invoking the security exceptions under Article 73(b)(iii) of TRIPS.

IV. CONCLUSION

This paper has attempted to shed light on the international obligations of test data protection under the TRIPS Agreement, particularly in the context of public health emergencies. By analyzing the scope of protection required under Article 39.3 of TRIPS, it has demonstrated how the undefined terminology within this provision allows WTO Members considerable policy space in shaping their regulatory approaches. A key contribution of this paper lies in its detailed interpretation of the phrase "unfair commercial use" and its implications for test data protection, an area that remains ambiguous in legal and policy discourse.

Furthermore, this paper has provided a novel perspective on the intersection of test data protection and compulsory licensing, arguing that public health considerations, especially during pandemics, justify an approach that balances the rights of originator companies with broader societal needs. Through an analysis of Articles 7 and 8 of TRIPS, as well as the Doha Declaration, this paper makes an original contribution by asserting that compulsory licensing of test data is a legally justifiable mechanism to ensure equitable access to medicines in times of crisis.

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[109] *Russia — Traffic in Transit* Panel Report, *supra* note 10, ¶ 7.138.
[110] *Id.* ¶ 7.139.

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Additionally, by examining recent WTO rulings on the national security exception, this study has introduced a theoretical framework for invoking Article 73(b)(iii) of TRIPS to suspend test data protection during public health emergencies. This interpretation is particularly relevant in the wake of pandemics, offering policymakers a legal basis to override intellectual property protections when necessary for safeguarding public health.

Overall, this paper not only clarifies the obligations of WTO Members regarding test data protection but also expands the discussion on how existing TRIPS flexibilities can be utilized in times of global health crises. By bridging legal analysis with contemporary public health challenges, this research provides a fresh contribution to the ongoing debate on intellectual property rights and access to medicines, with implications for future pandemics and global health governance.

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