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Access To Medicines With Reference To The Us-Morocco Fta Prohibition On Parallel Imports Of atented Pharmaceuticals

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INTRODUCTION

There has been significant apprehension since the inception of the World Trade Organization (WTO) in 1994, which integrated intellectual property rights into the international trading system through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), that the trading framework would globalise patent monopolies, making it more difficult for low- and middle-income countries to provide access to vital medications for all people in dire need.[1] The TRIPS Agreement establishes a regulatory "floor" of basic standards of protection for intellectual property that should be provided by all WTO members.[2] As a result, governments can seek stronger levels of protection in FTAs, just like the US has done in bilateral FTA negotiations with a number of countries.[3] These trade agreements are known as TRIPS-Plus US FTAs as they have more stricter and rigorous intellectual property protection standards than the TRIPS Agreement whilst still restricting the TRIPS Agreement's flexibility and freedom.[4] Accessibility to medications is a challenge in many nations for a multitude of reasons. Whilst the limitation of buying power and medical coverage is one aspect of the problem, global free trade agreements that regulate these nations also exert significant influence in hindering access to medications, especially those that are recently invented. The

[1] Sean Baird, Magic and Hope: Relaxing Trips-Plus Provisions to Promote Access to Affordable Pharmaceuticals, 33 B.C.J.L. & Soc. Just. 107 (2013), https://lawdigitalcommons.bc.edu/jlsj/vol33/iss1/4

[2] *Id.*
[3] *Id.*
[4] *Id.*

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purpose of this paper is to analyze the situation of Morocco prior and post the US-Morocco FTA and the various issues in the FTA that jeopardize the sale of cheap and generic drugs. As there have been no impact assessments of the FTA, it aims at assessing the current situation of the pharmaceutical industry and its accessibility to the masses of Morocco. The paper also compares the similar provisions of data exclusivity and compulsory licenses in the FTAs that the United States has with various countries like Dominican Republic, Vietnam, Thailand and Guatemala.

RESEARCH METHODOLOGY

The focus of this paper is on comprehending the multitude of issues that exist in the US-Morocco FTA which hamper the ability of generic pharmaceutical industry to exist in the market and subsequently eradicates their existence. This has been accomplished through the use of both primary and secondary sources. Reports from the US government and the WTO are primary sources. Secondary sources include a variety of research papers and publications.

TRIPS STANDARDS

In order to reduce the adverse impacts of patent rules on prices, the TRIPS Agreement allows countries to use certain key flexibilities, such as the granting of compulsory licenses in order to make cheaper generic versions of patented medicines or the parallel importation of patented medicines that are sold more cheaply in other countries. A country's ability to freely interpret and use these flexibilities was reaffirmed by the WTO Doha Declaration on TRIPS and Public Health of 2001.[5] The Doha Declaration expressly states that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, access to medicines for all."[6]

A few of the issues related to TRIPS Plus flexibilities were acknowledged in the 2001 Doha

[5] WTO, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 November 2001.

[6] *Id.*

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Declaration on the TRIPS Agreement and Public Health, which resulted in a significant explanation of TRIPS current policy flexibility. Following the Doha Declaration, parties devised the so-called "Paragraph 6 solution," which permits mandatory licences to be issued for medicines manufactured for sale to least developed nations, particularly those without manufacturing capability.[7] Despite the momentous judgement in Doha, there are still worries regarding the trading regime's compatibility with Sustainable Development Goal (SDG), particularly accessibility to medications.[8] TRIPS does not establish an uniform and international Intellectual property right system:[9] parties must adhere to these minimal requirements in whatever manner and methods they decide, and they are allowed to implement a more strict regime than that required under the Article 1 of the TRIPS agreement.[10] The WTO recognises the importance of nations meeting developmental and public health goals.[11] As a result, patent protection must lie inside a national realm in which governments are accountable for accomplishing these goals.[12] Patent protection "should contribute to the development of technical innovation and the transfer and diffusion of technology, to the joint benefit of producers and consumers of technological knowledge and in a manner conducive to social and economic welfare, and to guarantee a balance of rights and obligations," according to Article 7.[13] Thus, under Article 8.1 members can regulate on objectives such as promoting "public health,... and public interest in areas critical to their socioeconomic and technical development" .[14] Additionally, they can employ "appropriate measures" under Article 8.2 to "prevent right holders from abusing intellectual property rights or resorting to actions that unduly impede commerce or harm the international transfer of technology."[15] Thereby , the TRIPS agreement

[7] Rethinking Trade Treaties and Access to Medicines, Bu.edu (2019), https://www.bu.edu/gdp/files/2019/11/Trade-Report-2019-GDP-Center-3.pdf (last visited Nov 22, 2021).

[8] *Id.*

[9] Samira Guennif & Lalitha N., TRIPS Plus Agreements and Issues in Access to Medicines in Developing Countries Gidr.ac.in (2021), http://gidr.ac.in/pdf/WP-174.pdf (last visited Nov 22, 2021).

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Available from: http://www.wto.org/english/docs_e/legal_e/27-trips.doc

[11] Supra note 9

[12] *Id.*

[13] Supra note 10

[14] *Id.*

[15] *Id.*

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is not simply controlled by the absolute immunity of IPRs.[16] Indeed, WTO regulations governing technical trade barriers used to safeguard human health are addressed by either the Agreement on Technical Barriers to Trade (TBT Agreement) or the Agreement on the Application of Sanitary and Phytosanitary Measures (ASPA) (SPS Agreement).[17] In each of these agreements, public health is regarded as a legitimate basis for trade restrictions.[18] TRIPS agreement aspires to achieve effective IPR coverage that aligns with poor nations' public health objectives and the global diffusion of innovation. [19]

A government may override patents in order to achieve public health targets such as access to medicines, in compliance with the TRIPS agreement's provisions.[20]A government may utilise the patent's rights despite the patent holder's permission under Article 31b "in the case of a national emergency or other extraordinary circumstances, or in situations of public non-commercial usage" or under Article 31k "to remedy a practise determined to be anti-competitive".[21] However, the patent holder must be notified of the country's plan to deploy these rights over a reasonable period of time and must be compensated fairly.[22] As a result, in the event of an HIV/AIDS, malaria, or TB epidemic, or if prohibitive pricing or insufficient amounts of medicines are made accessible, a government might grant a compulsory licence (CL).[23] When there is no option of voluntary licencing, the CL method would be employed (the voluntary transfer of rights against royalties negotiated between actors).[24] A CL can be utilised by either a public or private entity.[25] A nation may enable a government entity or a private company to manufacture a drug in response to a national crisis and deliver the generic form of a drug at a cheaper cost and/or in larger quantities.[26] The Agreement recognises that countries have complete authority in defining what constitutes a national emergency.[27]

[16] Supra note 9
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] Supra note 10
[22] Supra note 9
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*

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THE US-MOROCCO FTA

Since 2001, the United States has signed 14 bilateral and regional free trade agreements with a total of 20 nations.[28] The inclusion of TRIPS plus requirements is a characteristic shared by these agreements.[29] The extended and stricter intellectual property rights required by such TRIPS plus requirements are likely to decrease accessibility to medications in poor and middle income nations significantly more than in high income countries.[30] The United States and Morocco have a bilateral trade deal known as the US-Morocco Free Trade Agreement. The agreement was signed on June 15, 2004, and the USMFTA Implementation Act was signed on August 17, 2004 by US President George W. Bush.[31] TRIPS-Plus requirements in US FTAs hinder the ability of destitute communities access to medications.[32] The parallels in US patent law and the TRIPS Agreement reflect the US's dominance in defining worldwide intellectual property principles.[33] Notwithstanding the United States' effectiveness in establishing universal intellectual property regulations, the TRIPS Agreement retains numerous flexibilities, including data exclusivity and compulsory licencing, which was confirmed by the Doha Declaration.[34] Due to the sheer discontent with the degree of intellectual property protection provided by the TRIPS Agreement, TRIPS-Plus measures have proliferated the US FTAs.[35]

ACCESS TO MEDICINES PRIOR TO THE FTA: A BACKGROUND

Before 2000, Morocco did not have any patent legislation on pharmaceuticals. This enabled the Moroccan pharmaceutical industry to flourish and develop into the second biggest pharmaceutical industry in Africa, after South Africa.[36] In 2000, the Moroccan pharmaceutical

[28] Free Trade Agreements | United States Trade Representative, Ustr.gov (2021), https://ustr.gov/trade-agreements/free-trade-agreements (last visited Nov 22, 2021).

[29] Correa, Carlos María. "Implications of bilateral free trade agreements on access to medicines." *Bulletin of the World Health Organization* vol. 84,5 (2006): 399-404.

[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] Supra note 1
[34] *Id.*
[35] *Id.*
[36] Trade-related intellectual property rights, access to medicines and human rights – Morocco, Www2.ohchr.org (2006), https://www2.ohchr.org/english/bodies/cescr/docs/info-ngos/access_to_medicines_and_hr.pdf (last visited Nov 22, 2021).

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sector was able to meet 72.2 percent of the country's demands by selling generic medications for 10 to 80 percent of the cost of similar brand-name medications.[37] In 2002, the Moroccan Ministry of Health's budget accounted for around 4.6 percent of GDP, general government expenditure as a proportion of overall health expenditure was 32.8 percent, and private sector health expenditure was 67.2 percent. Individual household out-of-pocket payments represented 74% of all contributions in this private expenditure.[38] As per Moroccan civil society organisations, individual household expenditures on medications in 2004 were comparable to $17 per person, with just 15% of the people protected by a health insurance plan that reimbursed the value of medications.[39] The Moroccan government announced its proposal for compulsory health insurance protections for the more financially downtrodden communities in 2005, with the goal of reaching 10 million people by 2008.[40]

Nevertheless, such a strategy would only be realistic if the government preserves adequate policy room to implement steps capable of lowering the cost of drugs.[41] This approach has been seriously compromised since the approval and execution of the US-Morocco FTA. The FTA raised a lot of concern since the start of the negotiations, especially from Moroccan[42] and international access to medicines advocates.[43] These groups spearheaded campaigns urging the Moroccan government to ensure that the final text of the FTA did not include IP rules that would harm Morocco's ability to ensure access to affordable medicines for all, in accordance with its obligations under the right to health. A further issue of concern was the lack of

[37] Association Marocaine de Lutte Contre le Sida (ALCS), Mémorandum de la société civile contre les restrictions de l'accès aux génériques dans l'Accord de Libre Echange, January 2004.

[38] WHO, National Expenditure on Health – Morocco, 2002, www.who.int/nha/country/MAR.xls

[39] Supra note 36
[40] *Id.*
[41] *Id.*

[42] Association Marocaine de Lutte Contre le Sida (ALCS), Mémorandum de la société civile contre les restrictions de l'accès aux génériques dans l'Accord de Libre Echange, January 2004.

[43] Médecins Sans Frontières – Maroc, Les Dangers des dispositions sur la propriété intellectuelle dans l'Accord de libre-échange entre Maroc/Etats-Unis pour l'accès aux médicaments essentiels au Maroc, January 2004.

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transparency and access to information regarding trade decision-making.[44] Although the government of Morocco organized meetings providing information to interested parties once the agreement was signed, this cannot substitute access to information and public participation in decision-making before the conclusion of a trade agreement.[45]

Despite various efforts, the final text of the FTA includes IP rules that go beyond the standard of protection required by the TRIPS Agreement.[46] Most importantly, these campaigns maintained that the FTA text would dismantle the flexibilities reaffirmed by the WTO Doha Declaration on TRIPS and Public Health such as compulsory licensing or parallel importation, and would introduce rules that curtail Morocco's ability to take measures to reduce the cost of medicines.[47]

In the face of criticism from international and national civil society, the US and Morocco tried to resolve public health concerns by exchanging side-letters reaffirming that the obligations under the IP chapter "do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency and national emergency."[48] Moreover, the letters also state the parties' commitment to the WTO 30 August 2003 Decision and implementation of a final TRIPS Amendment. However, these side-letters are not incorporated into the FTA and therefore do not override the strict IP provisions in the agreement that undermine access to medicines for the poor.[49]

ISSUES WITH THE US-MOROCCO FTA

[44] Supra note 36
[45] *Id.*
[46] *Id.*
[47] *Id.*

[48] Exchange of letters between Robert B. Zoellick, US Trade Representative and Taïb Fasi Fihri, Minister Delegate for Foreign Affairs and Cooperation, Morocco, 15 June 2004.

[49] Robert Weissman, Essential Action, Comments on the Intellectual Property Chapter of the US – Morocco Free Trade Agreement and the Impact on Access to Medicines, 8 April 2004.

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Many TRIPS plus clauses are included in the FTA chapter on IPRs:

1. "Exclusivity" of unreleased information

i) A 5-year monopoly

The FTA grants exclusive rights to data necessary for the licencing of a drug, resulting in a minimum 5-year marketing monopoly.[50] The objective of this sort of regulation is to create a monopoly for non-patented items (example, items for which patent applications have been refused) and to prevent generics from being registered.[51] for instance, if a government decides to circumvent patents and grant compulsory licensing for government usage.[52] According to the FTA, regulatory bodies need not register a generic using clinical trial data given by the brand-name firm for the first five years after marketing clearance, until they have the brand-name firm's permission (receiving such permission is highly improbable).[53] If the generic manufacturer wishes to register a generic variant prior to the end of the five-year period, it must repeat the clinical studies, which would be expensive, time-consuming, and unethical.[54]

ii) A new three-year renewable monopoly for new clinical information.

The Morocco-US agreement contains a new paragraph about rights given based on new clinical data.[55] Article 15.10.2 of the FTA allows for limitless renewal of exclusive rights by permitting for a three-year data exclusivity term for new applications of previously marketed products.[56] There is a strong risk that the manufacturers of fresh clinical information may try to prevent generics from being registered further than the 5 years of data exclusivity by claiming overlap with freshly authorised utilizations of their drugs, even when these generic versions are launched for prior usages.[57] In such circumstances, the legal steps required to reject a brand-name firm's claim may be complicated, expensive, and time-consuming.

[50] Mellouk O, Struggling to Balance Free Trade with Access to Medicines in the post-TRIPS Era throughout the Arab World Iprsonline.org (2005), https://www.iprsonline.org/unctadictsd/docs/Mellouk_ArabRD_Health.pdf (last visited Nov 22, 2021).

[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*

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2. Compulsory licences (CL)

Applying data exclusivity again, Article 15.10.4 prohibits the selling of generic copies of a protected product throughout the patent's term.[58] In this situation, a generic copy under CL cannot be offered for 5 years, but throughout the term of the patent.[59] Even in an emergency, such a clause renders the usage of CLs null and void.[60] As a result, the exemption to patent rights under Article 31 of the TRIPS Agreement is rendered completely ineffective.[61]

3. The expansion of patentability to include secondary applications and small modifications to well-known drugs.

Article 15.9.2 of the FTA broadens the patentability standards to include already well-known items for secondary purposes (like new usages).[62] This creates extremely low patentability requirements, which will result in the issuance of dubious and unjustified patents.[63] Morocco has relinquished its rights in accordance with TRIPS Article 27.3(b), which addresses the potential exemption of plants and animals from patentable subject matter.[64] It has also rescinded the TRIPS flexibility that allows nations to decide whether second medical applications for previously well-known elements are patentable.[65]

4. Extending the patent protection term

These FTA expansions will enable patents to last longer than the existing 20-year lifespan.[66] Under article 15.9.7 of the FTA, Patent extensions should be provided to accommodate any potential setbacks in patent registration.[67] Since the FTA does not specify what constitutes a "unjustified elongation" of the effectual protection term, the FTA conceivably prolongs the patent protection duration beyond the TRIPS-mandated 20 years.[68] The Member States concluded that a 20-year length of protection was adequate during the TRIPS negotiations, because patent registration and securing marketing authorization

[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*

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required considerable time.[69]

5. Incorrect patent applications

As per Article 15.9.9, "each party should give patent applicants with at least one chance to submit revisions, corrections, and observations in connection with their applications."[70]
This clause incentivizes patent owners to file frivolous patent applications. Article 15.9.9 requires governments to enable patent applicants to modify their patent applications: this creates an incentive to file insufficient patent applications and ask for broader patents.[71]

6. Patent-to-market approval linkage

The FTA's Article 15.10.4 creates a relationship between marketing approval and patent protection.[72] As a result, Article 15.10.4 firstly, requires regulatory bodies to restrict third parties from marketing patent-protected items.[73] Secondly, Regulatory bodies must notify patent owners of the identities of third parties seeking marketing permissions within the duration of the patent.[74] The FTA requires regulatory bodies to follow patent rules in a manner that they are unable to give marketing authorization for generic copies of patented products that are either produced locally or imported under compulsory licences.[75] It moreover requires under Article 15.10.3 that regulatory bodies to notify the patent owner if a third party applies for marketing approval and requires that the authorities compensate the patent owner with an extension of the patent protection duration if the product's registration was delayed.[76]

7. Parallel imports

[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*

In the pharmaceutical industry, parallel importation refers to the importation of patented medications that have lawfully been placed on the market in another nation without the approval of the patent owner.[77] Article 15.9.4 requires governments to prohibit parallel importation of patented goods.[78] However, this privilege is provided under article 6 of the TRIPS and reaffirmed in paragraph 5(d) of the Doha Declaration, which stipulates that nations are allowed to develop their own systems for intellectual property exhaustion.[79] Parallel importation allows nations to shop for the best possible pricing for items on the international market.[80] In the case of medicines, corporations may price discriminate across different regional markets, thus purchasing on the international market (or at least between nations of equivalent economic development) may allow governments to drastically cut their pharmaceutical expenses.[81] According to a footnote, this ban on parallel importation may be restricted to cases where the patent owner restricts importation through agreement or other means — but incorporating such terms of the contract is no hindrance to brand-name drug corporations, and essentially gives them the ultimate authority to ban drug reimportation. [82]

Parallel imports of pharmaceutical items are usually referred to as 'reimportation' in the US.[83] The reimportation of pharmaceutical items is currently prohibited in the United States, although legislation to legalise it is in the works.[84] There is widespread public support for reimportation, and federal states that wish to acquire cheaper pharmaceuticals from Canada are more supportive.[85]

8. The Deceptive 'letter of understanding'

In response to the mobilisation of civil society in Morocco and the United States against the FTA's intellectual property rules, a "letter of understanding" was communicated between the American trade representative, Robert Zoellick, and an official of the Moroccan government.[86] The letter is intended to ensure that the FTA's intellectual property obligations would not

[77] Supra 48
[78] *Id.*
[79] Supra 50
[80] Supra 48
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] Supra note 50

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jeopardise Moroccan access to pharmaceuticals.[87] In reality, because it is not contained in the FTA's language, this letter is secondary to the FTA's conditions.[88] This has no legal significance and cannot serve as a promise.[89] It also makes no claim to amend the chapter on IPR or to include exceptions to procedures that may obstruct the advancement of accessibility to medications.[90]

9. Patent revocation

The FTA also prevents third-party resistance when the patent application is being reviewed. Only when the patent is granted is it possible to raise objection.[91] The goal of this proposal is to reduce the possibility of patent revocation.[92] Exclusions include cases where there is no local manufacturing, no patent exploitation, and public health concerns, among others.

ACCESS TO MEDICINES IN MOROCCO AFTER THE US-MOROCCO FTA

As no impact assessment was undertaken whilst formulating the US-Morocco FTA, and even after 17 years since its ratification, there have been no actions taken by the Moroccan government to assess the economic impact of the US-Morocco FTA. Due the lack of initiative from the government, it is clear from the various statistics that the impact of the FTA was deleterious to the public health. In fact, in 2013, it was projected that 58 percent of healthcare funding was individually financed. When contrasted with other nations, the cost of medications in Morocco is noticeably higher.[93] Medications acquired in the private sector were determined to be 11 and 12 times more expensive than worldwide price levels for generic and originator drugs, accordingly, with some exceeding 215-fold.[94] When compared to living expenses, the cost of common treatments for widespread noncommunicable illnesses is significant.[95] In 2008,

[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] Tuck, C., Maamri, A., Chan, A.H.Y. and Babar, Z.-U. (2019), Editorial: Medicines pricing, access and safety in Morocco. Trop Med Int Health, 24: 260-263. https://doi.org/10.1111/tmi.13191

[94] *Id.*
[95] *Id.*

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the expense of one month's medication using the least expensive generic drug atenolol to treat hypertension was predicted to be nearly five days' pay, with original brands for some medicines reaching nearly eight days' wages.[96] According to estimates, an average appointment and prescription might account for one-third of a normal wage.[97] Despite being the second biggest in Africa, with significant large-scale investments in recent years, the Moroccan pharmaceutical business is concentrated by a few corporations.[98] A monopoly like this undermines the robust commercial competition needed to bring down pricing. Furthermore, although being widespread in other countries, many drugs do not have a generic availability in the private market.[99] High prices and the obligation to pay in cash up advance have been identified as important hurdles that make medications expensive.[100] In the United States, the world's richest economy, generic medications often grab 80-90 percent of a given drug's sales in the first year following launch, partly owing to generic substitute and other policies that encourage the purchase of generic drugs.[101] Retail price reductions due to the arrival of generic medications are dependent on the volume of rivals and can reach as high as 90% of the brand price prior to debut[102]. However, this is not the situation in many poor and middle-income nations, where generic drugs account for just 29.4 percent to 54.4 percent of all prescriptions.[103] According to a WHO study, even after the Moroccan government decreased the price of medications in 2014, the majority of Moroccans did not believe the price reduction was sufficient and it still had a significant influence on their capacity to purchase them.[104]

A COMPARISON OF US-FTAs WITH OTHER COUNTRIES

1. Guatemala

[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*

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TRIPS-Plus data exclusivity restrictions worsen the public health issues by limiting access to inexpensive drugs in a country where more than 50 % of the populace lives just under the official poverty line.[105] The United States-Dominican Republic-Central American Free Trade Agreement (DR-CAFTA) entered into force in Guatemala in 2006.[106] Strict data exclusivity rules in the DR-CAFTA have prevented a plethora of generic pharmaceuticals from accessing the Guatemalan marketplace, regardless of the notion that most of these treatments may successfully address important causes of disease and mortality.[107] For instance, Pfizer's Vfend costs 810 percent more than the generic equivalent. Vfend, on the other hand, is subjected to a fifteen-year data exclusivity period, preventing generic makers from accessing clinical information, stifling competition, and allowing Pfizer monopolistic price power.[108] Hence, the DR- CAFTA's strict TRIPS-Plus data exclusivity restrictions have decreased or eradicated generic pharmaceutical industry, resulting in an exorbitant price structure that makes crucial pharmaceuticals unattainable to a large portion of Guatemala's impoverished population.[109]

2. Vietnam

In 2000, the U.S. struck a trade deal with Vietnam. Between 2000 and 2005, the Vietnamese government tripled its health-care spending, most of which was ascribed to increased pharmaceutical expenses.[110] This is especially noticeable in the cost of antiretrovirals manufactured in Vietnam, which are 5 to 7 times more expensive than the lowest global costs for the identical medications.[111] Strict data exclusivity restrictions constrain access to drugs in Vietnam under such circumstances, aggravating an already severe public health crisis in a nation where 15% of the citizens live underneath the official poverty line.[112] Unrelenting TRIPS-Plus data exclusivity requirements, especially observed in Guatemala, limit the usage of clinical data for at least 5 years and up to 15 years, effectively prohibiting generic rivalry to

[105] Supra note 1
[106] *Id.*
[107] *Id.*
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Id.*

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brand-name pharmaceuticals.[113] As a result, large pharmaceutical corporations will be able to charge exorbitant rates, making access to inexpensive medications unreachable for low-income people who desperately require these life-saving drugs. [114]

3. Dominican Republic

The island of Hispaniola, which includes the Dominican Republic and Haiti, is home to about 85 percent of all HIV/AIDS cases in the Caribbean.[115] Despite the fact that it has never issued a compulsory licence, the Dominican Republic's intellectual property law has comprehensive compulsory licencing provisions.[116] The Dominican Republic also has a robust generic pharmaceutical sector, with generic manufacturers dominating around half of the national pharmaceutical marketplace.[117]On March 1, 2007, the Dominican Republic approved the DR-CAFTA. TRIPS-Plus elements of the DR-CAFTA have been described as being the most "onerous" of all US FTAs with Low and middle - income countries.[118] According to studies, the Dominican Republic would see a 9 -15% increase in pharmaceutical pricing as a consequence of the DR-CAFTA by 2027.[119] TRIPS-Plus patent restrictions in the DR-CAFTA substantially prohibit compulsory licencing by tying marketing clearance of generic medicines to patent holders' permission.[120] Therefore, even if a generic medicine company manufactured the physiological equal of Efavirenz by way of a compulsory licence provided by the Dominican Republic, the generic manufacturer would still need to acquire permission from the patent owner to distribute the generic variant of the pharmaceutical, which is exceedingly improbable.[121] Dominicans are compelled to take identical but more dangerous medications because crippling poverty prevents them from obtaining brand-name Drugs and mandatory licencing laws limit generic competition. [122]

[113] *Id.*
[114] *Id.*
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*

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4. Thailand

Thailand had an estimated 670,000 HIV/AIDS patients in 2002. The Thai government created a comprehensive health strategy that provided HIV/AIDS patients with universal access.[123]
In 2009, the initiative was effective in reducing HIV/AIDS mortality by nearly half.[124] The Thai government's capacity to encourage the accessibility of low generic pharmaceuticals was the most crucial component of the plan's success.[125] Nevertheless, accessibility to patented second-line medications was necessary to assure the viability of the HIV/AIDS programme in Thailand.[126] These copyrighted drugs are far more costly than their generic counterparts.
For instance, Abbott's Kaletra costs well over $2,000 per patient per year, restricting the Thai government's supply of the drug to 600 people out of 8,000 in dire need.[127] According to the World Bank, Thailand could bring down the price of second-line antiviral therapies by 90% by giving compulsory licences.[128] Thailand sought to negotiate lower costs for a number of medications, including Kaletra, but was unable to achieve a deal.[129] As a result, the Thai government planned to issue compulsory licences for two medications in 2006.[130] The U.S. and Thailand attempted to negotiate a trade agreement in 2004, but discussions were halted in 2006 due to a military takeover in Thailand.[131] The World Bank assessed that TRIPS-Plus elements in the planned US-Thailand FTA would have hampered Thailand's capacity to issue compulsory licences, costing more than $3.2 billion over a twenty-year period.[132]

CONCLUSION

The TRIPS agreement requires developing nations to establish a restrictive Intellectual

[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *Id.*
[132] *Id.*

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property right regime, with exceptions for the safety of public health and the promotion of medication availability. Nevertheless, as high-income countries are determined to increase severe IPRs protection and limit flexibilities, as they are devoted primarily to the establishment of market monopoly at the detriment of competition and ability to pay, limiting medicine accessibility. The paper showed that data exclusivity is successfully imposed through the US FTAs, restricting the introduction of generics, that would impair availability to medications in underdeveloped economies and also constrain price competition. By partaking in such trade agreements, poor nations lose freedom, notably in the health sector. As a result, it is critical that international institutions get increasingly proactive in analysing trade agreements to verify that they do not contradict national charters or global trade accords.