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TRIPS-PLUS REGULATIONS IN BILATERAL AND STATEWIDE TRADE AGREEMENTS: THEIR BEARING ON INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL TRADE

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ABSTRACT

Intellectual property (IP) related goods have become a source of concern in the global economy of trade and substantial exports and imports. A primary concern for IP-intensive goods is the issue of cross-border trade. Through a collective effort of the member nations of the WTO, the TRIPS Agreement has always served to regulate and facilitate the entire trading mechanism for IP-intensive goods, but more stringent provisions under TRIPS-Plus are also frequently followed to provide additional assistance, going beyond the minimum standards of protection. In such circumstances, patents play a crucial role in the business models of pharmaceutical sector. The matters of compulsory licensing regime and data exclusivity also create a point of discussion as pharmaceutical as an industry, hugely affect Bilateral and Regional Trade Agreements. This leads to the unveiling of the Doha Declaration, which was introduced with the underlying intention of providing additional guidance to the TRIPS Agreement. Simultaneously, this makes the parallel importation and patent revocation, an essential conversation. This research is an effort to understand the Free-Trade Agreements, US laws, and the role of TRIPS-Plus provisions in the global context of trade.

Keywords: Cross-Border Trade, Free-trade Agreements, IP-intensive goods, Parallel Importation, TRIPS-Plus.

INTRODUCTION

With the current pace of globalization and the rapid development of cross-border trade, goods and services along with Intellectual Property (IP) is moving across the globe in a borderless manner. The significance of IP-intensive goods and services

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in international trade could be judged by the fact that, they solely account for 80 percent of the total goods and services in world trade.[3]

Protection and enforcement of Intellectual Property Rights (IPR) have long been a part of international trade policies. After the signing of NAFTA in 1994 and the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) in 1995, international trade has undergone significant changes and trade policies have been utilized more frequently to promote IPR standards on a global scale. The TRIPS Agreement lays forth the fundamentals for protecting and enforcing IPR. The agreement seems to have been a temporary measure paving the way towards more permanent protections for IPRs.

At the first look, the establishment of minimum criteria and rigorous enforcement procedures for IP protection under the TRIPS Agreement seemed to have satisfied the expectations of the industrialized nation-states for a higher degree of IPR protection. But, in a deeper view after failing to achieve their objectives of a firmer capitalist IP reign over the world during WTO negotiations, the United States and other industrialized nation-states almost immediately began promoting the expansion into more legally binding regulations, expanded reporting, and tighter harmonization, significantly larger regulation methods, and a reducing of 'customization' & 'special as well as differential treatment' conferred to inventions.[4] Therefore, States advocating for a more robust protection of IPRs have switched their attention from International Conventions to bilateral and regional pacts. As a result, developed countries were already encouraging IP protection through bilateral and continental Free Trade Agreements (FTAs), while developing countries like India were failing to meet even the TRIPS standards. The United States is a frontrunner in this field, advocating for stringent IP protection than those mandated under 'TRIPS-Plus provisions'.

Preferential Trade Agreements (PTAs), such as economic collaborative partnerships and FTAs, have started including TRIPS-Plus provisions in recent years. The developing and least developed nations have started facing a variety of difficulties when TRIPS-Plus clauses are included in unilateral and bilateral free trade agreements. The problem with TRIPS-Plus is that it may be implemented in a variety of ways such as intentionally limiting TRIPS' flexibility, providing more protection than is required under TRIPS, altering obligations and rights under other international pacts, or introducing new concerns not covered by TRIPS.[5]

Potentially, the United States has started to shift its attention to bilateralism in an effort to reverse-engineer the fact-based and strategic earns assurances and greater freedom conferred to emerging nations by the TRIPS Agreement, by depleting or occasionally renouncing the TRIPS Agreement's least benchmarks. However, this does not give a whole picture of IPRs' origins and development. Initially, exclusive rights over intellectual property were awarded on a national level and utilized as an economic protectionist weapon to set up domestic manufacturing and export infrastructure.[6]

An alternate method of fortifying these pre-existing IPR is provided under the Additional Provisions for Trade in Intellectual Property Rights (TRIPS-Plus). The TRIPS-Plus clauses are based on the 'commitments that go above the minimum standard concept' with regard to the TRIPS

3 Paweł Folfas and Andżelika Kuźnar, *International Trade in Intellectual Property-Intensive Goods*, Warsaw School Of Economics (2 Aug. 2013), http://www.etsg.org/ETSG2013/Papers/137.pdf.

4 The launch: from Singapore to Doha, with a detour in Seattle, https://www.wto.org/english/res_e/booksp_e/historywto_11_e.pdf

5 Graham Dutfield, *To Copy is to Steal: TRIPS, (Un)Free Trade Agreements and the New Intellectual Property Fundamentalism*, Research Gate (Feb. 13, 2015), https://www.researchgate.net/publication/267997434.

6 Susy Frankel, *The Legitimacy and Purpose of Intellectual Property Chapters in FTAs* in Ross Buckley, Challenges To Multilateral Trade The Impact Of Bilateral, Preferential And Regional Agreements 185-199 (Vai Io Lo and Laurence Boulle ed., Wolters Kluwer, 2008), http://ssrn.com/abstract=1862686

Protocol, in contrast to the flexibilities under the TRIPS Agreement, which are in a sense a "limit" for the implementation of multinational treaties. The influence of this provision on existing and future multilateral discussions; the direct impact of one provision on another; and indirect impact of one provision on another are the three ways to assess the impact of this section on bilateral and continental trade pacts.

In theory, developing and least-developed nations should have ample room for creative interpretation because of the TRIPS Agreement's fuzziness, which is overseen by the World Trade Organization (WTO). In point of the fact, however, the circumstance is made more difficult by the fact that the capacity of emerging and less advanced States to make advantage of the flexibilities and opportunities provided by TRIPS is steadily diminishing. The WTO's dispute settlement case laws might be one possible remedy, although neither conflicts involving violations nor those involving non-violations of intellectual property are eligible for WTO arbitration. Since 2003, when the question of whether to or not broaden pro cases to the TRIPS Agreement was initially brought up in WTO ministerial conferences, there has been growing concern about this potential expansion. Thus, the question that arises is whether it is appropriate for powerful nations like the United States to use multilateral and regional forums to negotiate for their own benefits and get concessions from less developed countries. Devised and industrialized governments have developed effective measures, such as entering into bilateral and regional agreements, to keep countries in the developing world adhering to advanced and more rigid rules of intellectual property protection. Therefore, it is essential to evaluate the viability of such methods and any potential responses for emerging nations.

The TRIPS agreement established what have now become universal criteria for protecting IPR, sometimes known as the bare minimum for IP protection. The TRIPS-Plus provisions in this research go beyond the protections guaranteed by the TRIPS agreement. In keeping with the research's overarching goal, the researchers evaluate the possible effects of the TRIPS-plus clauses in light of the arguments put up by developed country governments in favour of them. Common examples of these TRIPS-Plus clauses include:

1. *"the extension of patent terms for delay due to regulatory approval processes and delays in issuing patents;*
2. *the requirement to provide patents for new methods of producing known products;*
3. *the patentability of life forms by elimination of Article 27 (3) (b) of the TRIPS Agreement;*
4. *the limitation of Compulsory License;*
5. *the prohibition of marketing approval for a generic drug during the patent term without authorization from the patent owner;*
6. *the protection of test data for pharmaceutical products; and*
7. *the limitation of parallel imports through license contracts."*[7]

The research evaluates the possible effects of these TRIPS-plus clauses in favor of developed country governments[8]. Due to the above prolongation, patent holders can now enjoy monetary advantages that were not accessible during the application phase. Noteworthy, that the US-Singapore FTA has pushed for this due to the increase in patenting difficulties.[9] As a result of the prolonged patent durations, customers will be deprived of the benefits of generic competition for

7 Uruguay Round Agreement: TRIPS

Part II — Standards concerning the availability, scope and use of Intellectual Property Rights, https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

8 *The Drug Price Competition and Patent Term Restoration Act of 1984* (Hatch-Waxman Act) 21 U.S.C. 355(b), (j), (l); 35 U.S.C. 156, 271, 282.

9 *US-Singapore Free Trade Agreement* (USSFTA) art. 16.7.7, 16.7.8, 16.8.4, May 06, 2003

medications that are less severe and less precise. Despite pharmaceutical monopolies, developing nations are equipped to deal with much more serious dangers. Furthermore, this development will imply that the patent holder has a robust commercial strategy long after the patent expires.[10]

Second, compulsory licenses are the norm in the IP system to ensure the public's health. Such licenses are typically utilized to find a amicable system between the interests of patent holders and the greater good of society.[11] However, obtaining this form of a license from the government might allow a third party to manufacture and sell an inferior quality product. WHO has recommended adopting such licenses to guarantee drug costs are in line with the local acquiring agency in order to "prevent patent rights abuse and a public tragedy."[12] Pharmaceutical prices have been reduced in countries where mandatory licensing is in place, countries such as the USA, Canada, and Brazil.[13]

Conversely, analysist of pharmaceutical companies considers this licensing as an unfair trade just because it uses the innovations sans permission. Companies in the drug sector are also opposed to this method[14] since it discourages risk-taking, investigation, and progress.[15] In spite of the TRIPS Agreement's capacities of negotiation, it is worth noting that nations that employ compulsory licensing are typically the target of economic blackmail. In the Doha Declaration on the TRIPS Agreement and Public Health, the WTO requested that its representatives utilize this lawfully provided tool to help make more low-cost drugs available to the public.

According to Article 31 of the TRIPS Agreement, every member state is authorized to issue compulsory licenses under certain conditions. It also lays out some of the reasons why member nations could give compulsory licenses while acknowledging that others may exist.[16] However, nations' discretion to pursue such a policy is frequently circumscribed by tools that have just one face. The US-Singapore FTA, as one example, provided requirements for the application of compulsory licenses, such as reserving such licenses during the emergency needs, for public non-commercial reasons, and on natural disasters. In all other cases, this agreement forbids the necessary nations to issue compulsory licenses. Using such licenses is now subject to stricter compensation requirements because of the US-Singapore FTA. The sharing of research results or expertise is prohibited by compulsory licenses which makes it harder for people in some nations to access the medication they require. According to *Kuanpoth*, fewer Thai, Vietnamese, Myanmar, and Cambodian patients would have

10 Jakkrit Kuanpoth, *Current Development and Trends in the Field of Intellectual Property Rights: Harmonisation through Free Trade Agreement*, Iprsonline.Org 14, http://www.iprsonline.org/unctadictsd/dialogue/docs/Kuanpoth_2004-11-08.pdf (last visited March 01, 2018).

11 *Undermining Access to Medicines; Comparison of Five US FTA's: A Technical Note*, Oxfam International, Oxfam Briefing Note, 9 (Jun. 2004), https://policy- practice.oxfam.org.uk/publications/undermining-access-to-medicines-comparison-of-five-us-ftas-a- technical-note-115054

12 *See* carlos m correa, *integrating public health concern into patent legislation in developing countries* 94 (south centre 2000), available at http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf

13 Yousuf A. Vawda, *Compulsory Licenses and Government Use: Challenges and Opportunities*, https://link.springer.com/chapter/10.1007/978-3-030-83114-1_3

14 Christopher Gibson, *Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 357 (2010); See *also* Subhasis Saha, *Patent Law and TRIPS: Compulsory Licensing of Patents and Pharmaceuticals*, 91 Journal Of Patent & Trademark Office Society 364 (2009).

15 Dipika Jain & Jonathan Darrow, An Exploration of Compulsory Licensing as An Effective Policy Tool for Antiretroviral Drugs in India, Https://Www.Researchgate.Net/Publication/259347671_An_Exploration_Of_Compulsory_Licensing_As_An_Effective_Policy_Tool_For_Antiretroviral_Drugs_In_India.

16 *Supra* note 10.

access to necessary medications as a result of the FTA between Thailand and the United States."[17]

Limiting parallel imports is the third point. Another method that developing countries use to obtain affordable remedies like compulsory licensing comprises bringing in cheaper, generic versions of proprietary pharmaceuticals from abroad for sale at home. The TRIPS Agreement allows this tactic, and each country has the right to regulate parallel imports as it sees fit. Furthermore, most FTAs between the US and other nations restrict the use of parallel importation techniques and other potential workarounds for developing countries.[18]

Limiting the ability to cancel patents is fourth point to consider. The Patent Term Restoration and Improvement Trade Agreement allows patent cancellation but does not specify any circumstances for doing so. U.S. free trade agreements forbid patent revocation because it might encourage nondisclosure, insufficient or illegal changes to the patent application, fraud, or dishonesty.[19]

According to *Palombi*, Article 27.1 of the TRIPS states that "the authentic interpretation of the term 'innovation' does not genuinely embrace spontaneous things, normal occurrences, and associated synthetic descendants."[20] To be patentable, an innovation must be "new," "entail an original creation," and "large-scale production," therefore this reading is consistent with this central tenet of patent law. Further according to Palombi, in industrialised countries, the majority of biotech inventions which are equal to or substantially analogous to spontaneous phenomena are antithetical to something and breach of TRIPS."[21]

The fifth is the safeguarding of confidential information. Pharmaceutical and agrochemical goods must be registered in most countries before being sold. The firms must collect and analyse data on the good's quality, and requirements for validity, security, and effectiveness before a product may be then identified as information gathered from examinations. In light of the time and effort invested in its collection, this information must be safeguarded.

According to the TRIPS Agreement, all member countries are obligated to supply secret information for advertising reasons and to avoid "unethical branding use" or "publication".[22] First-to-submit commercial authorisation information to a national pharmaceutical regulating agency is never afforded as information confidentiality protection under the TRIPS.[23] It allows participating countries to set their own standards for protecting sensitive experimental information. Generic drug companies can, in fact, rely on the data supplied by the innovator company in order to register their products with the FDA. In addition, US FTAs mandates any drugs to have ownership information for at least 5 years, and a 10-year period for agrochemicals. Likewise, this safeguards the original manufacturer's test data from being used by competitors. Additionally, under US FTAs, all material offered for promotional clearance, including formulations, dosage regimens, and unique indications for the well-known drug, must be fully protected. The capacity of a government to implement the rules

17 See Kristina M. Lybecker and Elisabeth Fowler, Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules, 37(2) The Journal Of Law, Medicine & Ethics 222-239 (2009).

18 Ibid.

19 US-Singapore Free Trade Agreement (USSFTA) art. 16.7.4, May 06, 2003.

20 PO Sub-Regional Workshop on Patent Policy and its Legislative Implementation, https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_skb_13/wipo_ip_skb_13_t10.pdf

21 Ibid.

22 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) art. 39.3, Apr. 15,

1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

23 Data Exclusivity and The Trips Agreement, Https://Www.Ifpma.Org/Wp-Content/Uploads/2016/01/Ifpma_2011_Data_Exclusivity__En_Web.Pdf.

of TRIPS Article 39.3 is hampered as a result.[24] The entry of generic pharmaceuticals to the market is further slowed by the extensive and pricey testing and certification process. Due to the lack of access to relevant and sufficient data, the chance of forced licenses is diminished as a consequence of proprietary protection. Data exclusivity indicates patent holder's monopoly has increased. As an added bonus, it imposes strict punishments, such as criminal sentencing for IPR breaches and violations, and it impedes the implementation of obligatory licensing and other protections for public health policies in developing countries that do business with the US.

Finally, the point is the patenting of living things. Almost every country in the club agrees that it's impossible to get a patent on a living thing. In actuality, however, patents have been and will remain to be issued on microbes and other forms of life. The premise of patent law as a whole has been tested by futuristic biotech breakthroughs and their uses. A question mark looms over this TRIPS agreement: "*whether these discoveries integrate within the notion of patentability overall, and whether to achieve collaborative inventive step standards in specific*" [25]. The fundamental issue at stake here is whether or not a patent may be issued for something as inherently human as a bodily component. By virtue of TRIPS, patents on life forms are possible – theoretically, however, if we follow the definition of an invention under Article 27.1 we can contend such a view. However, Carvalho argues that "patent is technology friendly,[26] as a result, equal treatment ought to be afforded to all forms of technological advancement."[27] The US inclines to highlight this principle in FTAs. For instance, a key provision of the FTA between the US and Singapore is according to Articles 27.2 and 27.3 (a) of the TRIPS Agreement, "every Member may restrict innovations from patentable subject matter solely as described in those Articles."[28] So, this would indicate that "including genes and gene sequences," all forms of life are patentable.

TRIPS-PLUS PROVISIONS

Provisions relating to market approval for patented drugs

> U.S. free trade accords increasingly include clauses that make it unlawful for national pharmaceutical control authorities to certify a generic variant of a drug held in the country without the authority of the patent holders. The following is sample language from a variety of contracts: [29]
>
> "Allowing a third party to conduct research on the topic of a party's subsisting patent to produce data in support of an application for marketing authorization of a pharmaceutical... If the Party allows exportation, the product may only leave the Party's territory if doing so is necessary to generate information to meet requirements for approval to market the product once the patent expires."[30]

As a major change from prior practices, this mandate means that the regulatory permission granted to a product through market approval of a drug's safety and efficacy is no longer tied

24 Part II- Standards concerning the availability, scope and use of Intellectual Property Rights, https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm

25 Ibid.

26 Nuno Pires De Carvalho, The Trips Regime Of Patent Rights 9 (2nd ed. Kluwer Law International 2005).

27 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) art. 27, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

28 US-Singapore Free Trade Agreement (USSFTA) art. 16.7.1, May 06, 2003.

29 Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, Research Gate (Nov. 2006), https://www.researchgate.net/publication/228154939.

30 Arts 19(5)(3) of CAFTA-DR; 17(9)(4) of US–Chile; 15(9)(6) of US-Morocco; 16(7)(5) of US-Singapore; and 14(8)(5) of US-Bahrain.

to the patent validity of the treatment. Thus, a drug's patent status has never been considered in determining whether or not it is safe, effective, and reliable enough to be marketed in a particular country. The fact that the organizations responsible for issuing patents and those responsible for giving administrative and commercial authorization cover wholly diverse terrain explaining why patent status is maintained distinct from regulatory approval.

Assessments and awards are made at patent offices, where the initial determination of whether the drug in question is inventive and original is made. But it is up to the National Medicine Regulatory Authorities to determine whether the medicine in issue meets the standards for quality, safety, and efficacy necessary for sale as a genuine medical therapy. Whether or not the requirements for a patent in that nation have been met - this is why NDAs have hitherto given little consideration to patentability. Therefore, a national drug regulatory authority's decision has never been influenced by the applicant's generic manufacturer's probable patent violation. Thus, it is usually the patent holder's obligation to take legal action against a generic producer who they think is infringing upon their patent. In order to stop the sale of allegedly infringing products and to receive financial compensation, patent holders are frequently forced to file a lawsuit against the suspected infringement. The validity of the patent must be established through a lengthy and expensive process before the plaintiff's rights may be enforced. Furthermore, TRIPS lends substantial support to the concept that IPRs are "personal assets," and it follows to rationale that anyone who possesses a personal interest is bound to protect it. For this reason, the regulatory authority's new function as an "enforcer" of a private right is very advantageous to the holder of that right.

For instance, alternative pharmaceutical businesses are not guaranteed protection under TRIPS in their pursuit of profit and market approval for inexpensive copies of patented active medical components. Experimentation, inquiry, and the right to prior use are all free from patent protection under Article 30. This clause has been used to advance scientific and technical endeavours by enabling scientists to get a better understanding of patented technologies through their usage. And it's what generic drugmakers use to sneak in marketing requests ahead of the patent expiration and avoid legal trouble together with the patentee. The Canada-Pharmaceutical Patents Panel decided that Article 30 provides legal protection for such a method.[31]

With this reading, state operations both before and after TRIPS are consistent with the research exemption, and Article 30 of TRIPS appears to enable the exemption. Furthermore, nations that use the TRIPS-recognized option of a compulsory license may be harmed by the relationship between market permission and patent validity, which delays the availability of generic pharmaceuticals. In cases where laws restrict the registration of generic pharmaceuticals before the patent lapses, it is not apparent whether a compulsory license may be given. There is a potential barrier to entry because even a firm that is granted an compulsory license to manufacture must register with the national drug supervising agency. To put it another way, the compulsory license would not go into effect if generics weren't first approved by the regulatory agency.[32]

Provisions relating to data exclusivity

To guarantee the safety, effectiveness, and sufficient quality of their product, manufacturers must apply for marketing and regulatory approval from their country's drug control agency. This government agency depends on the clinical studies and information that drug applicants voluntarily provide rather than conducting its own. This means that the original petitioner or the generic medication maker need not re-perform the exact clinical trials in order to submit an application for licensing of the identical drug. Alternatively, they

31 WTO Panel Report, Canada-Pharmaceutical Patents, WT/DS114/R, adopted 7 April 2000, at para 4.15 (also holding that manufacturing and stockpiling drugs prior to the exhaustion of patent protection is not a 'limited exception' under Article 30).

32 *Supra* Note 26.

might demonstrate that the medicine they wish to deliver is as secure and effective as the standard option. Without the requirement for expensive clinical trials, generic drug manufacturers may be able to bring their products to market more quickly and at cheaper costs.[33]

In accordance with the TRIPS Agreement, parties are not obligated to provide any data to a provisional application. Article 39.3 of TRIPS simply emphasizes the duty to prevent the "competitive economic usage" and "publication" of "unrevealed experiment or comparable information," given that such information is secret, represents "significant labor," and pertains to a "novel pharmacological species." Some pushback has been heard in response to this interpretation of TRIPS. Nothing in the TRIPS Agreement specifies either the limits or the modalities of protection, on the contrary, it is implied that each participant has to judge for themselves what constitutes an "unfair" situation.

Additionally, the definition of "new chemical entity" is not provided. But the United States' newest FTAs are designed to make its FTA allies more like the United States with American domestic Law by prohibiting reliance on clinical research and details provided by the preliminary applicant or/and by the successive applicant and the national authority while attempting to register the identical drug after the first enrollment period has expired. In most cases, a period of exclusivity of five years is negotiated in US FTAs. During the data exclusivity period, the generic producer conducts its own clinical studies and submits the results to the appropriate national authorities before the generic may be sold and distributed. The huge cost (sometimes in the hundreds of millions of dollars) of performing tests and acquiring clinical data is only one of several problems with this technique.[34]

This provision is problematic from a public health perspective, and it will be challenging for the generic industry to enforce such tight criteria. Producing generic versions of drugs would require generic drug manufacturers to invest large expenses to get this data, postponing the supply of the generic medication even if they were successful in doing so. When a product has previously been shown effective and safe in previous tests and clinical trials, some argue that doing more tests on the same product is unethical.

Despite the fact, the producer may not have tried to have the medicine registered in that nation, the United States has fought to have language added in various FTAs that enforce the length of time during which no information from a different country may be used. Generic manufacturers had no access to this data until the exclusivity period ended, and the country was unable to import the pharmaceutical in the issue. In addition, certain U.S. FTAs effectively forbid producers of generic medicines from relying on proof of the original medication's registration in another nation to show the safety and effectiveness of their own version. Obtaining marketing authorization may be delayed for up to five years from the time the product was certified in a nation that is not a party to the FTA in question.

Not only is marketing authorization for generic businesses not permitted at any point during the patent period, but TRIPS also prohibits compelled licensing. Preliminary results are protected by US FTAs for the term of a patent, as was previously established. Since the period of data exclusivity is likely to raise prices and postpone the product's debut to the market, it follows that this type of protection should be avoided. Competitiveness is stifled because, in certain situations, a generic producer is barred from registration in a country because of these regulations, information exclusivity can serve as a de facto patent and guarantee pharmaceutical companies a monopoly for a specified length of time. For the period of any exclusivity term, a country may be prohibited from access to the drug if that period is tied to the license

33 Vanessa Bradford Kerry & Kelley Lee, TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1892549/

34 R. Weissman, *Dying for Drugs: How CAFTA Will Undermine Access to Essential Medicines*, Essential Action (Mar. 2004), http://www.essentialaction.org/access/?p14.

in another country. Note that the data exclusivity term stipulated in FTAs will operate whether a drug is owned in the country. Data exclusivity periods have the effect of keeping prices high for consumers and discouraging competition when a patent is not present.[35]

Provisions extending the term of patent

For membership in TRIPS, a nation must focus on providing IP security for a period of at least twenty years from the patent's date of filing. Because medications as well as other medical supplies entail extensive testing and government inspection, pharmaceutical firms that wish to acquire patent rights typically do so at the early feasible phase of fundamental research, typically years before filing a petition for regulatory clearance. However, the prolonged eight-to-twelve-year patent & regulatory approval process will significantly reduce a company's monopoly duration on a new treatment. Patent term extensions as 'compensation' for 'unwarranted' delays in patent acceptance or product registration are not required of TRIPS members.

However, under the terms of certain US FTAs, pharmaceutical companies are compensated for any unreasonable delay caused by a Federal Drug Regulatory Agency in analyzing a request for registration, or by a patent and trademark office in assessing an application for a patent, by having the patent term extended by the identical length of time as the unreasonable delay.

It is worth noting that granting extensions for delays in registration and examination is an international standard practice, especially in industrialized nations. When looking at public health, however, the concept of what is reasonable raises some concerns for nations that are still developing. A reasonable delay may be greater than six years if national drug regulatory bodies and patent offices in underdeveloped nations do not have adequate resources. Here arises a question, whether the United States would find this kind of delay acceptable or not. These provisions lengthen the period during which pharmaceutical manufacturers are protected from generic rivalry, postponing the significant price reductions that pursue the emergence of generic competition; while this may not have significant ramifications for general populace wellbeing in advanced countries or even industrialized developing countries, it may have significant implications for general populace wellbeing in impoverished developing nations. Delays of this magnitude have the potential to exacerbate the public health concerns that are already afflicting many parts of the developing world. Given the complexity of applications and the resource constraints of patent offices and national authorities, it is concerning that the term unreasonable is not clearly defined, despite the fact that it makes sense to prolong patents when a prolonged waiting period would hinder the patentee from commercializing their creation.

Provisions limiting grant of compulsory license

Governments are allowed to temporarily override patents and enable the creation of generic copies of protected products through a process called "compulsory licensing," which is recognized as public health protection under TRIPS. In spite of the 2001 Doha Declaration, which maintained nations' freedom to utilize compulsory licensing and to decide the conditions warranting this action, the United States has pushed to constrain the flexibility through FTAs since the establishment of TRIPS. There are two types of limitations on mandatory licensing imposed by FTAs. As was said before, the data exclusivity restrictions in FTAs act as an indirect restriction on coercive licensing. Second, the reasons for issuing compulsory licenses are constrained by direct limits. For instance, in comparison to TRIPS, such provisions are worded negatively and restrict the utilization of compulsory licensing to specific situations. These situations include correcting an anti-competitive practise, public non-commercial settings, nationwide emergency situations and

35 Ellen't Hoen, Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity, https://link.springer.com/chapter/10.1007/978-3-030-83114-1_7

other extreme cases of urgency, and the inability to meet actual implementation.

In addition, the US-Singapore FTA further limits the use of compulsory licensing by increasing the amount of compensation needed (to 'reasonable and full' from 'sufficient' in TRIPS) and explicitly limiting the transfer of 'know-how' (a term not found in TRIPS). Know-how licensing agreements are commonly included in licensing arrangements to help the licensee get the most out of the patent, making the 'know-how' limitation even more crucial. If a licensee doesn't have access to the underlying 'know-how', the commercial value of the patent to the licensee is substantially lower.

However, the United States may not be using force to impose these prohibitions on compulsory licensing, and the agreements should not be taken as evidence of this. Both Australia and Singapore voluntarily limited the use of compulsory licensing to just the most dire of situations. Despite significant differences between the nations, the FTA draught text is strikingly like the US-Singapore FTA. As a result, a similarly restricted strategy may have far greater ramifications for public health. It is interesting to note that numerous nations negotiating the FTA may be adopting more restrictive regulations than are allowed under US domestic law by implementing TRIPS-Plus compulsory licensing clauses in their patent legislation. Although compulsory licensing is not a component of US patent law, it is a crucial remedy in antitrust lawsuits and can be found in other US laws such as the Clean Air Act and the Atomic Energy Act. As a result, patent owners in nations that take a more limited approach to compulsory licensing than the United States has more protections under foreign law than they do under U.S. law.

Provisions limiting parallel importation

When a patent holder sells a product to a buyer and resells the product to a second customer in another nation, this practice is known as parallel importing. This occurs when the cost of the imported good is less than the cost of producing or importing the identical same legally into the nation once transportation and tariff costs are included in. The capacity of a patent holder to engage in price discrimination across national lines is undermined by parallel importation, which may have a devastating effect on the profits of multinational corporations. Each WTO member has the right under TRIPS to develop its own system of exhaustion of intellectual property rights, and the Doha Declaration reaffirmed this right.[36] Parallel importing is therefore not in and of itself a violation of TRIPS.

Once a product has been on the market anywhere in the world, the IP holders no longer have any say over what else can be done with the IP or the product. There is therefore no prohibition against the importing nation reselling the drugs it bought at a discount to the original market or to any other market to make money. Attempts to lessen parallel imports are risky even with the necessary permission.

As a result, the United States has been pushing for FTAs that prohibit or severely restrict parallel imports into its member countries. Parallel importation is prohibited by Article 15(9)(4) of the US Free Trade Agreement with Morocco and Article 17(9)(4) of the US Free Trade Agreement with Australia, although both agreements permit the restriction to be limited to situations where the patent holder has set limits by agreement or other methods. Despite the aforementioned caveat, the rule may effectively restrict parallel importation and, in essence, permit patent holders to segregate markets and perpetuate price discrimination under contract law. Article 16(7)(2) of the United States-Singapore Free Trade Agreement further limits parallel imports by letting patent holders prevent imports into either nation if they have been imported elsewhere illegally.

Such actions by developing nations would run counter to the essence of the Doha Declaration and undermine efforts to increase patient access to healthcare. Hence, it is necessary to ensure that the

36 Doha Ministerial Declaration, WT/MIN (01)/DEC/1, adopted 14 November 2001, at para. 5(d).

medications supplied to poor nations at reduced costs are utilized to alleviate their health crises and not merely to a market prepared to offer a larger cost for the drugs.

ANALYZING THE VALIDITY OF THE TRIPS-PLUS PROVISIONS

When it comes to intellectual property rights (IPR), most FTAs between developed and developing nations include the TRIPS-Plus Standard for all IPR categories, including patents. Developed nations want a higher level of IPR protection than is afforded by the multilateral agreement, thus they enforce this 'TRIPS-Plus' requirement in FTAs with their trade partners from poor countries. Not only do the Regional Comprehensive Economic Partnership Agreement (RCEP)s' patent rules contain TRIPS-Plus elements, but the RCEP's implementation of those terms has been explicitly struck down. To ensure that the Agreement is followed by all the Parties, RCEP requires the formation of sub-commissions on IPR to oversee the Agreement's operational structure and its implementation. If you compare India to its trade partners, it is observed that the country does not develop nearly as much new technology, and the rate at which its citizens file patents is far lower. To that end, a number of laws in the field of patent needs to be modified so that they are consistent with RCEP. These include the provisions on prior art, patentable and un-patentable innovations, sentencing, parallel imports, the exhaustion principle, and others. To fulfil its obligation under a bilateral agreement, India should revise the Patent Act of 1970 with a view toward safeguarding its own interests rather than those of other nations.

Although it is possible that the United States is utilizing bilateralism to undercut the actual and strategic advantages, protections, and possibilities of developing nations by undermining or even overturning TRIPS, this perspective fails to properly comprehend the larger, more chronological context of IPRs. Examining the bigger picture reveals that TRIPS is not the final word on intellectual property rights as some had hoped, but rather is part of a greater cycle in which developed countries use bilateralism, regionalism, and multilateralism to further their preferences and safeguard concessions from numerous different nations, particularly developing nations.

In the evolution of IP rights, it is observed that stages of cooperation, nationalism, and internationalism. In the past, IPR and trade-related concerns were granted on a national scale and used selectively to boost domestic manufacturing and exports. As a means of addressing the system's shortcomings, early bilateral trade and Friendship, Commerce, and Navigation (FCN) treaties adopted the principles of Most Favored Nation (MFN) and National Treatment (NT), both of which included IPRs. As the 1800s progressed, however, trading nations negotiated a web of bilateral agreements that made MFN and NT mostly ineffective.[37] When the 'spaghetti bowl' agreements became intractable, the authorities and experts accepted the liberties that must be legally recognized in an international environment.[38]

Building upon bilateralism, these initiatives close loopholes and make IPRs more consistent. As a result, in 1883, the Paris Convention for the Conservation of Industrial Property (patents, trademarks, and industrial designs) and the Berne Convention for the Preservation of Literary and Artistic Activities were ratified in 1886.[39] These and other IP-related accords were eventually overseen and controlled by the World Intellectual Property Organization (WIPO).

Governments resorted to bilateralism and drafted Bilateral Investment Treaties (BITs) to

37 Stephen Ezell and Nigel Cory, *The Way Forward for Intellectual Property Internationally,* https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally/

38 J. Bhagwati, *Reshaping the WTO*, 168 Far East Econ Rev 25 (2005).

39 Berne Convention for the Protection of Literary and Artistic Works (Paris Act), 1161 UNTS 30, revised 24 Jul 1971 and Paris Convention for the Protection of Industrial Property, 20 March 1883, 13 UST 2, 828 UNTS 107, as last revised at the Stockholm Revision Conference 14 July 1967, 21 UST 1538, 828 UNTS 303.

protect numerous private rights, including IPRs, when the GATT 1947 failed to do so. Bilateral Investment Treaties (BITs) negotiated in the 1970s and early 1980s had more clear language related to IP, suggesting a return to bilateral relations in IP protection.

At the same time, the WIPO and its numerous treaties kept multilateralism alive, amidst widespread criticism that the organization represented primarily the interests of poor countries and so failed to adequately protect IP. As a result, more developed countries avoided holding their conferences, and the trend of signing BITs continued.[40] In reaction to government policies and the recession of the late 1970s and early 1980s, however, wealthier nations synchronized a transition away from multilateralism, while least developed nations allowed their multilateral advantage to fade. In light of the United States' realization that counterfeit goods were costing the country between USD 43 and 61 billion annually and the inability of BITs to sufficiently enforce intellectual property rights (while counterfeiting and other breaches persisted), the venue was moved.[41]

CONCLUSION AND SUGGESTIONS

The TRIPS-Plus provisions and subsequent standards are of-course, developed with U.S. domestic interests in mind. The United States is making a demand, and its counterpart can either accept it, conditionally recognize it in exchange for a concession from the United States or reject it outright. This strategy has been met with criticism from some observers, but it is really not different from any other negotiation strategy. It should come as no surprise that the TRIPS-Plus terms contained in US FTAs (or internationalizing) are identical to aspects of US domestic law. US law that gives the President the authority to negotiate trade agreements, the 'Trade Promotion Authority' or so-called 'fast track', states that the promotion of an IP regime that "reflects standard of protection similar to that found in United States law" is a stated US negotiation objective.

The United States has considerable negotiating influence in international FTAs due to its status as a flexible trading partner. Most rich nations pressure developing countries to include TRIPS-Plus elements in their FTAs with them. The negative effects these clauses have on domestic legislation are left to these nations to deal with.

Because of the potential for conflict between the TRIPS-Plus rules and the governing national legislation, it is recommended that both countries complete an impact study before entering FTAs. It is important to keep in mind that each country has its own unique set of circumstances, including its own legal system, judicial viewpoint to international commitments, economy, etc., that will affect its capacity to meet the goals of the TRIPS-Plus provisions.

Any disagreements that may arise from the application of TRIPS-Plus rules must be settled through a reliable dispute resolution system. If there is a solid system in place, developing nations will have a better place to settle disagreements about the application of arbitrary rules. In order to promote growth and development among nations, it is necessary to construct international law on the subject of dispute resolution with respect to TRIPS-Plus clauses and establish a norm based on precedent.

40 J. Braithwaite and P. Drahos, Global Business Regulation (CUP, 2000).

41 F. Abbott, *Commentary: The International Intellectual Property Order Enters the 21st Century*, 29 Vanderbilt J Transnatl L, 471-473 (1996).