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Trips Agreement's Obligations And Their Repercussion On Developing Countries During Emergency Situations

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Abstract

In accordance with Articles IX.3 and IX.4 of the World Trade Organization Agreement, the worldwide epidemic of Covid-19, the largest health tragedy to hit the world in the previous century, has unquestionably been a "exceptional situation," killing millions of people and causing unparalleled economic and social suffering around the world. As the epidemic spreads, nations will need to come up with creative solutions to not only boost vaccine manufacturing, but also guarantee that vaccines are distributed on time and at a reasonable cost. The TRIPS Agreement's obligation to satisfy strict IP requirements may not be an option in this scenario. International agreement TRIPS is part of the World Trade Organization (WTO) and aims to create a common level of intellectual property protection for all members (WTO). When TRIPS was signed into law in 2001, the Uruguay Round of global trade negotiations came to an end. Before finally caving in to intense pressure from wealthy country governments, poor country leaders resisted the completion of the accord on philosophical and economic grounds. Despite their protests, practically all governments in poor countries have enacted TRIPS-compliant policies, many of which are stricter than required under TRIPs. To explain the puzzle, this article aims to test if the many theories of international rule compliance, including realism, neoliberalism, and constructivism, are all correct. A closer look at domestic politics in developing nations is needed in order to assess their propensity to cooperate, since none of these hypotheses can explain the observed variance.

Key words: WTO, Compulsory Licensing, patent, Developing Countries, COVID-19.

Introduction:

Developing countries will find it very challenging to abide by the terms of the TRIPs Agreement due to its content and implementation method. While patents and copyrights were previously covered by the agreement, it was the first time the WIPO had specified minimum standards for member countries' domestic intellectual property laws.[1]

There are also standard procedural criteria for IP administration and maintenance under the TRIPs Agreement, which regulate state enforcement procedures. Due to the fact that the TRIPs Agreement is a component of the World Trade Organization, member compliance with the agreement's obligations is subject to binding arbitration. As a result,

[1]Mitsuo Matsushita, Thomas J. Schoenbaum, Petros C. Mavroidis, Michael Hahn. Third edition. Oxford, United Kingdom: Oxford University Press, 2015. Print.

the agreement has significant external enforcement. As a result of the TRIPs Agreement, national laws will be harmonized while enforcement mechanisms will be boosted.

International trade has become more concerned with intellectual property protection as the value of intellectual property increases[2] and technology's role to competitiveness grows.[3] Through their efforts, US corporations were able to persuade the governments of the United States, Europe, and Japan that intellectual property was an important subject to handle during the Uruguay Round of international trade discussions.[4]

In addition to philosophical and economic objections, the developing countries argued against TRIPs. A Western developed civilization perspective on intellectual property was promoted by the TRIPs Agreement, they reasoned these critics. In the majority of developing countries, intellectual property rights (IPRs) are seen as a shared resource, but in certain developing countries, such as those that wish to attract high-quality foreign direct investment, IPR protection is preferred.[5] Moreover, unlike liberal traditions that emphasize material gain over social and cultural value, most traditions in developing countries place a premium on social and cultural value over material gain.[6]

Adopting developed nation norms of intellectual property protection may have negative consequences for developing countries. They feared that extending current intellectual property protection and expanding protection to new sectors would raise royalty payments for use of developed nations' intellectual property.[7] The World Bank projected in 2001 that fully implementing the TRIPs Agreement will cost developing nations an additional $20 billion in technology payments.[8] As a result, implementing TRIPs means transferring money from developing countries' consumers to developed nation's multinational companies.[9]

They were also concerned about the costs of the TRIPs Agreement, which necessitates the implementation of new laws and the improvement of enforcement mechanisms, such as judicial systems.[10]Despite their protests, poor nations ultimately agreed to the TRIPs

[2]Robert J. Gutowski, The Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match Made in Heaven, 47 BUFF. L. REV. 713 (1999).
[3] South Centre, The TRIPs Agreement a Guide for the South: The Uruguay Round Agreement on TRIPs, (Geneva) 10 (1997).
[4] Stubbs, R., & Underhill, G. R. D. (1994). *Political Economy and the Changing Global Order* (1st ed.). McClelland & Stewart.
[5] Olwan, R. M. (2013). Intellectual Property and Development: Theory and Practice. Germany: Springer Berlin Heidelberg.
[6] Marron, D.B., & Steel, D.G. (2000). Which Countries Protect Intellectual Property? The Case of Software Piracy. *Economic Inquiry*, *38*, 159-174.
[7]Robert J. Gutowski , The Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match Made in Heaven, 47 BUFF. L. REV. 713 (1999).
[8] Graham Dutfield, 'To Copy is to Steal': TRIPs, (Un) free Trade Agreements and the New Intellectual Property Fundamentalism, The Journal of Information Law And Technology (2006) 1.
[9] ibid
[10] Michael J. Finger and Philip Schuler, Implementation of Uruguay Commitments: The Development Challenge, the world economy, (2000) 23(4) 521

agreement due to financial incentives and the significant consequences of not doing so. For all parties, the penalty of not agreeing was especially significant because of the United States and the European Union's determination that the Uruguay Round Agreement would be an unified endeavour, with all of the separate accords as "integral elements" (GATT).[11] In the event that the Uruguay Round Agreement, which includes TRIPs, is not accepted by any nation, that country would lose access to the US and EU markets that it had previously enjoyed under the GATT.[12] As a result, the Uruguay Round and the TRIPs Agreement were reached under duress.

Since the United States is notorious for failing to protect intellectual property rights, they believed that adopting the global TRIPs Agreement would protect them from any unilateral sanctions. The Uruguay Round Agreement provided greater access to wealthy country markets for developing country goods such as agricultural and textiles.[13]

TRIPS during COVID-19 pandemic

The TRIPS talks were acrimonious throughout the Uruguay Round, which ran from 1986 to 1994 and culminated in the foundation of the World Trade Organization (WTO) in 1995.[14] Developed nations, particularly the United States (US), campaigned for the TRIPS agreement with the support of their pharmaceutical multinational companies. These nations' pharmaceutical industry anticipated this outcome if they had better cross-border IP protection managed by a multilateral agreement. Developing nations, on the other hand, were averse to a WTO deal on intellectual property. By leveraging trade penalties and concessions in agriculture and textiles, rich nations successfully induced developing countries to accept IP into the Uruguay Round of talks.[15] People's right to health has been a contentious issue since then.[16] In support of the idea that IP protection encourages innovation, proponents argue that national and international regulations should be tightened to make it more effective. Some believe that patents prevent the introduction of inexpensive vaccinations and drugs in underdeveloped countries, limiting people access to health care, which is counterproductive.[17]

In light of Covid-19, the argument has moved to centre stage. An unmistakable silver lining has emerged from the crisis: vaccinations and therapies developed against Covid-

[11] Richard H. Steinberg, In the Shadow of Law or Power? Consensus-Based Bargaining and Outcomes in the GATT/WTO, international organization (2002) 56(2) 360.
[12]john h. Barton et al, the evolution of the trade regime: politics, law and economics of the GATT and the WTO 66 (2008).
[13] Frank Emmert, Intellectual Property in the Uruguay Round Negotiating Strategies of the Western Industrialised Countries, Michigan journal of international law (1990) 11 ,p. 1385
[14]Gervais, D.J. (1998) The TRIPS Agreement: Drafting History and Analysis. Sweet & Maxwell, London.
[15] Lester, Mercurio, B., & Davies, A. (2018). World trade law : text, materials, and commentary (Third edition.). Hart Publishing, an imprint of Bloomsbury Publishing Plc ; Hart Publishing.
[16]Sarah Joseph, *Blame it on the WTO: A Human Rights Critique* (Oxford: Oxford University Press, 2011), pp. 241.
[17]Medecins Sans Frontieres (MSF), *A Fair Shot for Vaccine Affordability*, *21 Sept 2017*, Geneva, Medecins Sans Frontieres, 2017.

19 are protected by the TRIPS agreement. The vaccine or drug may only be manufactured, sold, and used by the patent holder for a period of 20 years after the date of the patent application.[18] This level of protection may make it more difficult to make vaccinations widely available, therefore prolonging the outbreak. Ending the epidemic will need a massive vaccination effort, not just a few vaccinations, and it is up to us to make it happen. Due to growing vaccine nationalism fears, where wealthy countries purchase vaccinations ahead of others, the job is enormous, and it may derail the aim of providing two billion doses of vaccine to low- and middle-income nations.[19]

Taking this into consideration, it is important to understand India and South Africa's joint WTO proposal, which calls for a temporary relaxation of IP rights for Covid-19 vaccines and drugs.[20] Because of intellectual property rights, immunizations and medications may be more expensive, according to this theory.[21] Consequently, India and South Africa have requested that certain TRIPS rules be "waived" by the General Council of the World Trade Organization in order to prevent, contain, or cure the Covid-19 virus at a time when vaccine production must be increased to meet demand. This request has been made by the TRIPS Council of WTO.[22] Covid-19 medications, vaccines, and other treatments may be patented or licenced by WTO member nations during the duration of the waiver granted by the World Trade Organization (WTO). This will protect nations' vaccination programs from being branded unlawful under WTO rules.

Other developing nations have joined as co-sponsors of the initiative since then.[23] The TRIPS Council has had official and informal discussions on this topic during the past five months. Many wealthy nations are wary about surrendering IP rights, thus a consensus is unlikely. Covid-19 vaccine manufacturing would not increase if intellectual property rights were suspended, according to their opinion.[24] For sure there are flexibilities built into the TRIPS Agreement to ensure that patent rights are balanced with the right of people to health.[25] According to the author of this document, these options are woefully inadequate.

Indian Scenario of TRIPS and Effect on pharmaceutical Market during COVID-19.

Opponents of the TRIPS waiver request from India and South Africa claim that the demand to suspend IP responsibilities is unnecessary since the TRIPS Agreement

[18]Article 33 of the TRIPS Agreement
[19]Chris Kay and Haslinda Amin, "Vaccine Nationalism Threatens WHO's 2021 Goal of 2 Billion Doses", *Bloomberg Quint*, March 17, 2021.
[20]Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19, Communication from India and South Africa, IP/C/W/669.
[21] ibid
[22] ibid
[23]Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic, *World Trade Organisation*, February 23, 2021.
[24]Rich, developing nations wrangle over COVID vaccine patents, *Reuters*, March 10, 2021.
[25]Bryan Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review", *SSRN Working Paper*, (2021).

includes numerous flexibilities that may be utilized to meet public health emergencies.[26] These options are included in the TRIPS Agreement. For example, under the TRIPS Agreement, governments have the power to grant licenses for the use of patents throughout the life of the patent without the permission of those who own them. This authority is known as the compulsory license. Under Article 31, a government may authorize the use of a patent for its own purposes (i.e. non-commercial public usage). TRIPS flexibility measures were employed in 100 various ways by 89 countries between 2001 and 2016 to stimulate the production of generic drugs at acceptable rates, including compulsory licencing.[27]According to similar results, several LDCs took advantage of the extended transition period granted by the TRIPS Agreement another substantial TRIPS flexibility.[28]

Even if these flexibilities are adequate for coping with the present epidemic, assuming that they are would be a grave mistake. All nations do not benefit equally from the same TRIPS flexibility, such as a required license. Compulsory licenses may be useful in pharmaceutical manufacturing nations, but many LDCs lack the industrial capacity to use them. Nations that may utilize compulsory licensing to manufacture patented medicines, such as India, are always under pressure from industrialized countries to not do so. There are many examples of this. For example, the US government attacked India when it granted a compulsory license to Bayer to manufacture a generic version of its cancer medication in 2012.[29]

Compulsory licensing, as previously stated, does not provide any meaningful flexibility for nations without industrial capability. If a compulsory license is granted, a country's internal market may be its primary focus, as stated in TRIPS Article 31(f). As a result, generic medications made under a mandatory license are unable to leave the country. Article 31 of the TRIPS Agreement does not include a mechanism for compulsory licencing for countries with limited pharmaceutical production capability. Doha Declaration on TRIPS and Public Health paragraph 6 acknowledged this issue in 2001. There is a statement that says, "We acknowledge that WTO members with inadequate or no pharmaceutical manufacturing capacity may have difficulty using TRIPS compulsory licensing effectively." We direct the TRIPS Council to identify a quick fix and report back to the General Council before the end of 2002." By waiving Article 31(f) and 31(h), the WTO General Council allowed nations to export medicines made under obligatory license in countries without the manufacturing capability.[30]Article 31 of the TRIPS agreement,

[26]Bacchus, "An Unncessary Proposal: A WTO Waiver of Intellectual Property Rights for Covid-19 Vaccines", Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review".
[27] 't Hoen, E. F., Veraldi, J., Toebes, B., & Hogerzeil, H. V. (2018). Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001-2016. *Bulletin of the World Health Organization*, *96*(3), 185–193. https://doi.org/10.2471/BLT.17.199364
[28]Article 66.1 of the TRIPS Agreement.
[29]"US Attacks on India's Patent Laws", *Médecins Sans Frontières*, January 21, 2015.
[30]Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".

which went into force on January 23, 2017,[31] made the 2003 decision final after being modified in 2005. As can be shown, TRIPS flexibilities were insufficient in dealing with all instances of drug shortages since they required both a waiver and an amendment.

A large number of people believe that this amendment has addressed the issue of developing countries not having enough manufacturing capacity and therefore being unable to afford pharmaceuticals; however, there are still concerns about the lengthy procedure countries must go through in order to import and export medicines.[32] The exporting nation must guarantee that the medications created under a compulsory licence are exported exclusively to the country to which they were issued; the medicines must be clearly distinguishable by colour or form; only the quantity required for the eligible importing country's needs is made; and the importing country must notify the WTO's TRIPS Council.[33] Due to these restrictions, generic pharmaceutical companies are less likely to produce medicines with export permits.[34] Because nations with limited manufacturing capacity tend to be smaller, there are less economies of scale that can be reaped to entice generic manufacturers to ship medicines to such countries.[35]

Article 31 was deemed impractical by India and South Africa in their proposal to resolve the issues raised by Covid-19. Article 31 long and onerous processes would only impede countries' attempts to implement universal immunization since many of them lack pharmaceutical manufacturing capacity and thus need Covid-19 vaccines for their populations. Following the processes outlined in Article 31 for a large number of nations at the same time would cause a significant slowdown in vaccine exports, making them prohibitively expensive for countries in the midst of a pandemic. Because of the sheer size of the issue and the enormous global need for vaccinations, the TRIPS flexibility is impractical.

Licenses granted by patent holders to generic firms on mutually agreed-upon conditions are an example of voluntary licensing. For instance, India's Serum Institute has licence of the AstraZeneca Covid-19 vaccine, which was developed by AstraZeneca. It is essential to note that voluntary licensing are often cloaked in secrecy, with the patent holder having final say on such matters as who will get the medicine and how third-party vendors will be chosen. In the same way, AstraZeneca's voluntary license to Serum Institute may be

[31]TRIPS Agreement (as amended on 23 January 2017).
[32]Patents versus Patients, five years after the Doha Declaration,. (2006). *Oxfam International).*, *Oxfam Briefing Paper 95*,(November 2006,).
[33]"Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".
[34]Harris, D. (2011, March). TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing",. *Journal of Intellectual Property Law*, *18*(2), 367.
[35]Carlos M Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?" South Centre, Policy Brief, 57 (January 2019).

considered to be similar. As a result, many other businesses would need an update as well, which would need a non-exclusive agreement that is unlikely to materialize.[36]

According to the majority of evidence, patents are of negligible value, but foreign patenting may promote technology transfer and local economic integration in certain industries and circumstances.[37] As a result, the commonly cited rationale for implementing the TRIPs Agreement is merely a presumption, and the overwhelming evidence shows that it is false. However, as Penrose points out, patent protection may not be necessary for all industries. Pharmaceutical patent protection through TRIPs may be a way to help develop this industry, as well as facilitate the transfer of technology and the associated investments that go along with it. TRIPs will be fully operational in developing countries a few years after 2005, at which point it will be clear whether or not this rumour is true.

In developing countries, accessibility and affordability of pharmaceuticals are critical considerations. There is a lot of sickness and disease going around, and a lot of people are poor and unemployed. India had a strong patent law while it was a British colony, which was primarily implemented to benefit British patent holders. Consequently, "Indian drug prices were among the worlds most expensive, partly because 90% of the pharmaceutical market was controlled by foreign owned companies and India was totally dependent on imports." Different fears existed in India before and during the Uruguay Round among the Indian public and the Indian pharmaceutical industry. There was widespread concern that TRIPs would drive up the cost of drugs in India, where the population is disproportionately comprised of the poor. There was concern in the pharmaceutical industry that it would be replaced by multinational corporations that would gain control of the entire patented drug manufacturing market in India.

Developed countries were dissatisfied with Indian patent law before TRIPs. As a result of India's low-cost drugs sold worldwide, U.S. pharmaceutical companies suffered significant losses. The multinational pharmaceutical companies whose products were being reverse engineered and mass produced in India asserted that this amounted to theft.[38] America was on a mission to curtail this heist in India. Western countries' monopolistic privileges allowed pharmaceutical firms in the West to reap large profits. In contrast, the western market was getting oversaturated as time passed. The pharmaceutical industry began to see developing nations like India as excellent outlets for its goods. Due to a high incidence of disease and an enormous population that has been growing quickly and continues to do so, there was a strong need for pharmaceuticals. Indian population growth now exceeds the total population of a

[36]Thambisetty"Vaccines and patents: how self-interest and artificial scarcity weaken human solidarity".LSE British Politics and Policy ,February 9th, 2021

[37] E, Penrose. International Patenting and the Less Developed Countries. 1973 Sept E.C.S, p.9

[38] E, Henderson. TRIPs and the Third World: The Example of pharmaceutical patents in India, Westlaw [1997], 19(11), p. 15.

complete country when nations in Europe or Africa are included. The patent market is just 10% of this population, even if the wealth gap is still wide.[39] Due to a lack of patent protection in India and many other developing nations, pharmaceutical companies in the industrialized world were forced to compete with the lower-cost generic versions of their patented drugs. That the Indian businesses say the advocates of TRIPs wanted to make sure multinational pharmaceutical corporations from rich nations had a substantial if not complete stake in developing country markets is unsurprising is not unexpected. TRIPs proponents merely point out that they were compelled to do so in order to safeguard their industry's vulnerable sectors. Whatever the case, TRIPs includes clauses that may have a significant negative impact on India's economy.

There are a number of specific requirements in Article 31 of TRIPs, all of which must be adhered to in order to ensure that any patent is not used without the permission of the patent holder. There would be significant restrictions on India's ability to issue compulsory licenses as a result of these regulations.

Compulsory licenses will not be granted if the patent fails to satisfy "the reasonable needs of the public"[40], among other criteria. Except in cases of national emergency, exceptional urgency, or for non-commercial public usage, compulsory licenses will only be given to those who have made an effort to acquire a license from the patentee. The government may only issue automatic compulsory licenses in these three situations, according to section.[41] In addition, the license may only be granted for a short period of time and must be restricted in scope.

Conclusion

The author will conclude this paper on two pints (i) currently the world community included India had one goal in mind: to put a stop to the Covid-19 epidemic. Vaccination rates must rise rapidly if this goal is to be achieved. The growing demand for vaccines necessitates higher production, which must be followed by more equitable distribution. This cannot be achieved just via the use of a waiver of intellectual property. Increase vaccine production and make it available to everyone will need building institutional capacity in many countries, eliminating systemic bottlenecks, and implementing administrative and legislative reforms. Increasing vaccine production may need a TRIPS waiver, on the other hand.

When faced with such a daunting task as a vaccination pandemic, voluntary initiatives by few pharmaceutical companies may be insufficient. While manufacturing-capable nations may take use of TRIPS flexibilities like compulsory licensing, countries without such capacity, particularly LDCs, cannot. Because of the enormous demand, pharmaceutical firms have little need to fear losing their investment if IP rights are suspended. Public

[39] M. Saurastri'It 's time for an effective patent regime in India ' MIP 1996/97 vol 65 pg 34
[40] section 84,India's Patent Act 1970,
[41] TRIPs Article 31 (b).

funding and public money are often used by pharmaceutical firms, for example in the creation of the Covid-19 vaccine. As a result, it's fair to distribute the rewards to the whole public. As the World Health Organization properly points out, no one is safe until everyone is safe in a fast-moving epidemic. As a result, the international community must use all available tools, including a temporary waiver of TRIPS.

(ii) Realism, neo-liberal institutionalism, and constructivism have all been shown to be unsatisfactory in poor countries' compliance with TRIPs. Constructionists were wrong to foresee widespread non-compliance due to developing countries' scepticism about the validity of the TRIPs Agreement or their difficulty to harmonise national norms. A number of poor countries have already taken steps to comply with TRIPs and/or established national legislation that is more stringent than what is required under TRIPs. The implementation of TRIPs Plus protection also does not cleanly match to US requests for stronger protection of intellectual property rights in particular nations. TRIPs However, as expected by neoliberal institutionalism, intellectual property protection in poor countries has improved as a result of WTO complaints against them, although these cases are rare.

As a result of this unaccounted-for variation across nations and IPR categories, systemic methods to explaining compliance with the TRIPS Agreement by developing countries are deemed inadequate. These findings indicate that domestic politics have a significant impact on whether and how external pressures are converted into acquiescence. The author of this article has provided a framework for examining how external forces affect compliance.

Particular focus is placed on mobilizing actors and if entrenched interests may serve as veto players to prevent policy changes from taking place. In this way, the significance of domestic politics in explaining compliance is being highlighted more and more in the field of International Relations.

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