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**Issue
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TRIPS WAIVER PROPOSAL - AN ONGOING DEBATE

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TRIPS Waiver Proposal - An Ongoing Debate

In early October 2020, India and South Africa submitted a proposal to the WTO TRIPS Council to waive the implementation and enforcement of IP requirements in the TRIPS agreement. The waiver was proposed in the hopes of “uninterrupted collaboration in development, production and supply” towards COVID-19 treatments. This would allow the free sharing of technology and know-how, enabling manufacturers across the world to produce enough medical products including vaccines for the world’s population.

Key Issues

1 The Waiver Proposal has quickly brought to light the divide between the global North and global South, and between LMICs and HICs.

2 Countries opposed to the waiver are largely HIC's showing reluctance to change a system that suits them and their pharmaceutical companies so well; but also Brazil¹ and Mexico have not supported

3 Despite the waiver proposal obtaining sponsorship of 60 WTO members and support of another 40, the TRIPS and WTO General Councils have not progressed due to opposition from wealthy Northern governments.

4 Arguments from Southern nations are sound and are based on ample proof from past experiences and the current dire situation of vaccines shortage. However, these are being disregarded by Northern nations who insist on stonewalling tactics and are relying on trite defenses.

1- However the worsening crisis in Brazil has led to the passing of a Senate a bill to suspend patent protection for COVID-19 vaccines, tests and medications during the pandemic. The bill will be next considered by the lower house of the Brazilian Congress. See Brazil Senate votes to suspend patent protection on COVID-19 vaccines (2021, April 30), retrieved April 30 from <https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30/>

Introduction

On October 2nd, 2020, India and South Africa submitted a joint proposal for a “waiver from certain provisions of the TRIPS agreement”. The proposal states that while certain flexibilities are available under the TRIPS agreement, they are not a blanket enforcement applicable to every nation. Many flexibilities- such as compulsory licensing- operate on a “product by product and country by country” basis. Additionally, many countries have national laws which create barriers for compulsory licensing, along with inadequate ability to manufacture locally. Therefore, India and South Africa are calling for a waiver of obligations related to the protection and enforcement of patents, copyrights, industrial designs and trade secrets to allow freedom of operation to scale up the production and supply of medical products for the prevention, containment and treatment of COVID. The pandemic has been raging for more than a year without a “meaningful global policy solution” in place that will ensure access.

Adoption of the waiver proposal would enable the suspension of TRIPS provisions and it would expedite the freedom of operation for the diversification of manufacturing base through local production and ensure equitable drug access². Additionally, implementation of the TRIPS waiver can be done according to a country’s needs and means and not require the amendment of intellectual property legislation. For example, emergency and disaster management legislations can be relied on to operationalize the waiver at the regional level and implementation can take places in a phase-like manner, similar to how lockdowns have been put in place³.

After a series of deliberations there is no consensus regarding the adoption of the waiver proposal. Countries remain divided over support for the waiver and a consensus has not been reached. Currently 60 developing and least developing member countries co-sponsor the waiver proposal with the support of

2- Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19- Communication from India and South Africa [Letter to Council for Trade-Related Aspects of Intellectual Property Rights]. (2020, October 2).

3- Response to questions on intellectual-property challenges experienced by members in relation to COVID-19 in Document IP/C/W/671 [Responses submitted during TRIPS Council Meeting, WTO]. (2021, January 15).

another 40. The main opponents of the waiver are developed nations including the European Union, the UK, Australia, Japan, Norway, and surprisingly, Brazil. The Trump Administration opposed the waiver but the Biden Administration that is under growing public pressure domestically and globally showed a shift in the US position in an informal TRIPS Council meeting in April. It recognized that the “TRIPS agreement provides the right to grant compulsory licenses,” and it “respects its trading partners’ rights to grant these licenses in a manner consistent with the provisions of the TRIPS agreement” adding that it looked forward to hearing about hurdles in using TRIPS flexibilities⁴.

Historically, the US is known for its notorious undermining of the use of compulsory licenses especially through use of its “Special 301” Report. This is an annual review of the global state of intellectual property rights protection and enforcement, conducted by the Office of the United States Trade Representative (USTR) since 1989 under a domestic law, the Trade Act of 1974. This Report “reflects the Administration’s resolve to encourage and maintain effective IPR protection and enforcement worldwide”. Although this is a unilateral domestic law and measure, and therefore not in line with the WTO that was set up to prevent unilateral trade actions and sanctions, the US has consistently used its Special 301 report to intimidate developing and also other developed countries that use their TRIPS flexibilities for public health purposes⁵. It remains to be seen if the Biden Administration will be significantly different as the industry lobby against the waiver is intense⁶, and the annual complaints are intensifying⁷.

4- TRIPS waiver proposal being held hostage on “ideological” grounds. (2021, April 24). Retrieved May 1, 2021, from <https://twn.my/title2/wto.info/2021/ti210214.htm>

5- See compilation of Special 301 Reports 1989 to 2020 with highlights on submissions related to use of TRIPS flexibilities for public health and access to medicines. Knowledge Ecology International <https://www.keionline.org/ustr/special301>

6- Drug lobby asks Biden to punish foreign countries pushing for low-cost vaccines. (2021, March 4). Retrieved on May 1, 2020 <https://theintercept.com/2021/03/03/vaccine-coronavirus-big-pharma-biden/>

7- See Submission by the Pharmaceutical Research and Manufacturers of America. Retrieved on May 1, 2020 <https://www.regulations.gov/comment/USTR-2020-0041-0039>

Opposing Viewpoints

Opponents of the waiver have been engaging in “stonewalling”⁸ tactics to delay progress and question the validity of the proposal. While the opposing group has concurred on the need to distribute safe and effective therapeutics and vaccines and distribute them “equitably around the world”⁹, they continue to block the waiver proposal.

The UK in particular stated the proposed waiver was an “extreme measure to address an unproven problem”¹⁰. The arguments against the waiver are centered mostly on the fact that IP rights and patent protection provide incentives to invest in R&D on medicines, treatments and other technologies. The opposition insists that IP systems have not been proven to be “genuine barriers”¹¹ to accessing vaccines and other technologies related to COVID-19. Developed nations emphasize on available flexibilities within the TRIPS Agreement and the Doha Declaration as a solution to the health crisis at hand, such as the usage of compulsory and voluntary licenses. As Brazil stated, the opposition believes that “solutions can be legitimately sought within the system”¹². The US has highlighted the Biden administration’s commitment to a “global response”, specifically in reference to their \$4 billion donation to the COVAX facility¹³ and how it will play out its position remains to be seen as pressure mounts on the Biden Administration to support the waiver.

For example, the Biden Administration has been under pressure from 250 civil society organizations and prominent US Congressmen to support the TRIPS waiver proposal. However, in retaliation to this growing support, on March 29th a coalition of business groups called on the Biden Administration to “reject”

8- Developing countries call for text-based negotiations on trips waiver. (2021, February 8). Retrieved February 19, 2021, from <https://twn.my/title2/wto.info/2021/ti210204.htm>

9- TRIPS waiver proposal being held hostage on “ideological” grounds. (2021, April 24). Retrieved May 1, 2021, from <https://twn.my/title2/wto.info/2021/ti210214.htm>

10- Interventions from Co-sponsors. (2020, November 20).

11- Interventions from Co-sponsors. (2020, November 20).

12- Interventions from Co-sponsors. (2020, November 20).

13- Developing countries call for text-based negotiations on trips waiver. (2021, February 8). Retrieved February 19, 2021, from <https://twn.my/title2/wto.info/2021/ti210204.htm>

the waiver. Additionally, major representatives from Big Pharma companies wrote an open letter to President Biden urging his administration to “maintain longstanding support for innovation and American jobs by continuing to oppose the TRIPS waiver”.

On April 15th an Open Letter was published by a large number of former Heads of State and Nobel Laureates calling on President Biden to waive intellectual property rules for COVID-19 vaccines¹⁴.

However the USTR in her statement at the WTO virtual conference on April 14th stated that “there are many aspects of the institution of the WTO and its rules that have not adapted to a changed world, a changed membership, changed practices and expectations. We must ensure that this time of crisis and suffering leads to breakthroughs and progress”¹⁵.

In a major press conference in Washington DC on April 23rd , US lawmakers including Senators Bernie Sanders and Tammy Baldwin, Representatives Earl Blumenauer, Chuy Garcia and Jan Schakowsky, as well as leaders of labour, public health, faith and other CSOs delivered two million petitions to urge President Biden to join 100 other nations in “supporting a temporary waiver of WTO rules that now give a few corporations monopoly control over where and how much COVID-19 vaccines and treatments are made.”¹⁶

14- Open Letter: Former Heads of State and Nobel Laureates Call on President Biden To Waive Intellectual Property Rules for COVID Vaccines

15- <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/april/ambassador-katherine-tais-remarks-wto-virtual-conference-covid-19-vaccine-equity>)

16- Big Pharma to block TRIPS Waiver at WTO, citing China and Russia. (2021, April 27). <https://twn.my/title2/wto.info/2021/ti210415.htm>

Supporting Viewpoints

Proponents of the waiver proposal have taken time to repeatedly highlight specific issues that have arisen as a consequence of strict IPR during the pandemic and to address the repetitive questions from the opponents.

First, the supporters of the waiver have acknowledged that many countries have adopted TRIPS flexibilities and have passed national legislation that would make the usage of compulsory licensing easier. However, there are still shortcomings within existing laws for compulsory licensing, and new needs have arisen as a result of the scale and spread of the COVID-19 pandemic.¹⁷

Second, the proponent group has made clear the vast complexity of IPR that underlies vaccine R&D. Past experiences have shown how patents can be applied for at almost every step of vaccine “development, production and use”¹⁸. These include patents on materials used, manufacturing processes, the final product, filling and packaging methods, and vaccine administration itself. Furthermore, lesser-known trade secrets become a barrier to access and production especially for vaccines and monoclonal antibodies. Trade secrets can include the manufacturing process of vaccines, test data, and formulae¹⁹. A combination of patents and trade secrets can make crucial vaccines virtually inaccessible for years.

Finally, the mRNA platform technology that has been employed to make vaccines has over 100 background patents on it²⁰. As a result, even if one vaccine manufacturer refuses to enforce its patents over the technology- as Moderna has done- it would make little difference on the other patents in existence and offers no “legal certainty” that other manufacturers can use the platform.

17- Response to questions on intellectual-property challenges experienced by Members in relation to COVID-19 in Document IP/C/W/671 [Responses submitted during TRIPS Council Meeting, WTO]. (2021, January 15).

18- Response to questions on intellectual-property challenges experienced by Members in relation to COVID-19 in Document IP/C/W/671 [Responses submitted during TRIPS Council Meeting, WTO]. (2021, January 15).

19- Kerry Cullinan & Elaine Ruth Fletcher, Cullinan, K., & Fletcher, E. (2020, November 25). Philanthropy alone will not ensure global access to covid-19 vaccines - South Africa's take. Retrieved February 19, 2021, from <https://healthpolicy-watch.news/mustaqeem-de-gama-qa-philanthropy-will-not-fix-lack-of-vaccine-access/>

20- Response to questions on intellectual-property challenges experienced by Members in relation to COVID-19 in Document IP/C/W/671 [Responses submitted during TRIPS Council Meeting, WTO]. (2021, January 15).

Co-sponsors of the proposal- South Africa, India, Indonesia, Kenya, Egypt and Pakistan- have also provided robust and specific rebuttals to the opposition claim that barriers imposed by IPR do not exist and that solutions can be found within the TRIPS flexibilities.

Kenya's argument emphasized on the large amounts of public investment that has gone into R&D on emerging infectious diseases, including COVID-19. For example, 80% of past R&D on coronaviruses, MERS and SARS, has come from high-income countries²¹. Between 2016 and 2018, a total of US \$110 million was spent, of which only 0.5% of investment came from private industries²². This past research on coronaviruses is what has helped current research accelerate so that a timely solution is found to the pandemic.

South Africa rebutted against the workability of the TRIPS flexibilities in light of the current health crisis. The delegate stated that voluntary licenses that are allowed under the TRIPS agreement are available, but come attached with many terms that end up favoring the licensor. Such terms restrict access or favor wealthy countries²³. South Africa went on to highlight the danger of bilateral deals being made between countries and pharmaceutical nations, which undercut the efforts of compulsory and voluntary licensing. Moreover, these deals are highly opaque and the details are "mostly unknown"²⁴. The delegate warned against especially problematic bilateral deals because they reserve excess supplies of vaccines that are available in limited amounts for a small number of countries or populations. South Africa's rebuttal also mentions the vagueness of pharmaceutical companies' pledges to not enforce patents. For example, Moderna announced that it would not enforce patents "while the pandemic continues". However, this is an unspecified period of time and does not make clear what Moderna intends to do post this period with respect to pricing or licensing.

21- Interventions from Co-sponsors. (2020, November 20).

22- Interventions from Co-sponsors. (2020, November 20).

23- Interventions from Co-sponsors. (2020, November 20).

24- Interventions from Co-sponsors. (2020, November 20).

South Africa went on to highlight specific instances where patents and IP rights have blocked access to therapeutics, drugs and vaccines²⁵. The delegate used evidence such as the case of Gilead attempting to procure orphan drug status for Remdesivir, further extending the patent on it. They also mentioned the many monoclonal antibody candidate therapeutics under patent protection. Another example was the issue of the Netherlands being unable to obtain a liquid buffer needed to run COVID-19 testing. Pharmaceutical company Roche had the recipe for the buffer but initially refused to provide it, limiting the Netherlands' ability to conduct mass testing in a timely manner.

Lastly, intellectual property disputes are already emerging on the horizon with respect to COVID-19 medical products. Vaccine developers Pfizer and BioNTech are facing a lawsuit from Allele Biotechnology. The former accused the latter of using their mNeonGreen fluorescent protein to develop the Pfizer/BioNTech vaccine without Allele's permission.

India echoed its fellow co-submitter South Africa, by demonstrating the limitations of TRIPS flexibilities. The delegate stressed that information and awareness surrounding TRIPS flexibilities in areas other than patents- such as copyrights, industrial designs, and trade secrets- is poor and are therefore rarely implemented. Furthermore, India stated that many countries lack "institutional capacities to utilize such flexibilities"²⁶. Lastly Article 31bis has proven to be cumbersome to use, and has only been used once, back in 2006. This shows it is an unfeasible option in a situation that is very time-sensitive.

India went on to emphasize that the proposed waiver is optional- those members who feel the TRIPS flexibilities will provide for a COVID-19 response can choose not to implement the waiver at a domestic level. However, they should not come in the way of those who do support the waiver and unhindered sharing of technology and resources with respect to COVID-19. In addition, India highlighted the rather temporary nature of the COVAX initiative and the ACT-Accelerator. Both initiatives are only meant to address the "initial, acute state of the pandemic" in

25- Interventions from Co-sponsors. (2020, November 20).

26- Interventions from Co-sponsors. (2020, November 20).

order to delay collapse of healthcare systems and provide vaccines for 20% of LMIC populations²⁷. Even with such minimal goals, both initiatives are struggling to obtain adequate funding. Only 15% of their funding needs have been met so far.

These evidence-based arguments have since been reiterated several times at TRIPS Council meetings²⁸.

Where does the TRIPS Waiver Debate Currently Stand?

The former chair of the TRIPS Council, Ambassador Xolelwa Mlumbi-Peter from South Africa, had acknowledged the divided stance on the waiver proposal, with little to no movement. (Ambassador Dagfinn Sorli of Norway took over as chair of the TRIPS Council on March 11th; Norway is an opponent of the waiver.)

At the TRIPS Council meeting on March 10th, 2021 co-sponsors of the waiver indicated that they want to move towards text-based negotiations and not be stuck in circular discussions. Additionally, South Africa mentioned in its statement that the co-sponsors had been holding bilateral meetings with various WTO members, both with supporters and those who held concerns about the waiver proposal²⁹.

Of note, South Africa further reiterated the issues of voluntary licensing as a ‘solution within the system’, and stated that “passing this waiver makes ethical, epidemiological, and economic sense”³¹. Additionally, South Africa pointed out the unfeasibility of compulsory licensing, given that developing countries have faced repercussions for using such flexibilities in the past³².

27- Interventions from Co-sponsors. (2020, November 20).

28- Strong support for TRIPS waiver amidst opposition by Big Pharma. (2021, March 12)

29 Developing countries call for text-based negotiations on trips waiver. (2021, February 8). Retrieved February 19, 2021, from <https://twn.my/title2/wto.info/2021/ti210204.htm>

30 Thiru, B. (2021, March 11). 10 March 2021: South Africa raises the banner for the TRIPS waiver at the WTO. Retrieved April 05, 2021, from <https://www.keionline.org/35578>

31 Thiru. B. (2021, March 11). 10 March 2021: South Africa raises the banner for the TRIPS waiver at the WTO. Retrieved April 05, 2021, from <https://www.keionline.org/35578>

The fate of the TRIPS Waiver is still undecided, and further discussions are scheduled to take place in June at the next formal meeting of the TRIPS Council. The TRIPS Council chair is expected to propose informal sessions dedicated to discussing the TRIPS waiver proposal before that.

Pandemic Preparedness Treaty: An Alternative to the TRIPS Waiver?

On March 30th 2021, 25 countries, the European Union and the WHO joined together in their demand for an international pandemic preparedness treaty that would be applicable to all future pandemics. The treaty aims to “strengthen national, regional and global capacities”³³ as a way to ensure resilience in the face of future pandemics.

Specifically, this treaty aims to work on early detection and prevention of pandemics, better response to pandemics by strengthening healthcare systems, and ensuring equitable access to “medical solutions, such as vaccines medicines, and diagnostics”³⁴. Additionally, the treaty would ensure access to information on virus pathogens, and necessary technology to combat pandemics³⁵. Finally, the treaty aims to improve transparency, accountability, and “shared responsibility in the international system”³⁶. Issues like access to information on virus pathogens could be undermining the policy space of the global south by creating a legal obligation to share the pathogens without corresponding obligations to share the benefits of research and development such as the vaccines and diagnostic kits technologies.

32- Thiru. B. (2021, March 11). 10 March 2021: South Africa raises the banner for the TRIPS waiver at the WTO. Retrieved April 05, 2021, from <https://www.keionline.org/35578>

33- Council of the European Union. (2021, April 07). An international treaty on pandemic prevention and preparedness. Retrieved April 07, 2021, from <https://www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/>

34- Council of the European Union. (2021, April 07). An international treaty on pandemic prevention and preparedness. Retrieved April 07, 2021, from <https://www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/>

35- Afp. (2021, March 31). World leaders push for pandemic preparedness treaty. Retrieved April 6, 2021, from <https://www.dawn.com/news/1615599/world-leaders-push-for-pandemic-preparedness-treaty>

36- Council of the European Union. (2021, April 07). An international treaty on pandemic prevention and preparedness. Retrieved April 07, 2021, from <https://www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/>

Supporters of the pandemic preparedness treaty include Germany, Britain, France, South Korea, South Africa, Indonesia, and Chile. Other countries such as the US, China, Russia and Japan have not signed on yet³⁷.

Interestingly enough, some of the main signatories of the treaty- the EU, Korea, and the UK- are still in staunch opposition to the TRIPS waiver, which is an immediate solution to ramping up global production of diagnostics, therapeutics and vaccines. The treaty calls for “accountability and transparency” and “ensuring equitable access to medical solutions”, both of which are also aims of the TRIPS waiver. Therefore, a pandemic preparedness treaty stands in stark contrast to the blatant failure of international cooperation and the hoarding of vaccines by wealthy western nations, who are the main supporters. Such actions have delayed timely treatment to a majority of developing countries. The pandemic treaty could be a diversionary strategy to take away the attention from the current pandemic’s acute shortages of medical products including vaccines caused by intellectual property monopoly.

37- Afp. (2021, March 31). World leaders push for pandemic preparedness treaty. Retrieved April 6, 2021, from <https://www.dawn.com/news/1615599/world-leaders-push-for-pandemic-preparedness-treaty>



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