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COVID CRISIS & PATENT WAIVER – A SAGA

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ABSTRACT

The COVID-19 pandemic has undoubtedly been the biggest calamity in recent times. The pandemic put to test not only the global supply chain and infrastructure but also the national and international disaster-management capacities. These challenging times compelled the world to tackle the problem from a global perspective.

Ergo, with several joint efforts, the countries were able to collaborate, construct and finally implement an international decision with respect to intellectual property rights, which enabled the world to address the crisis as one.

In this article, the authors aim to discuss the proposals for intellectual property (IP) / patent waiver and the nuances of WTO's Ministerial Decision. The authors also highlight the decision's effectiveness in addressing the issue of the accessibility of resources to combat the dreadful pandemic.

Keywords: pandemic, World Health Organization, vaccines production and supply, global vaccine equity, United Nations Development Programme, IP waiver, Trade Related aspects of Intellectual Property Rights (TRIPs), patent waiver, global vaccine market report

INTRODUCTION

With the World Health Organization (WHO) categorizing COVID-19 as a 'pandemic' on March 11, 2020[1], the world was confronted with an unparalleled crisis of massive scale. The then WHO Director-General Tedros Adhanom Ghebreyesus' remarks rightly and clearly outlined the circumstances and challenges the world faced due to the onset of the pandemic. He said:

[1]https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020; accessed on 05.04.2023.

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"Some countries are struggling with a lack of capacity.
Some countries are struggling with a lack of resources.
Some countries are struggling with a lack of resolve."[2]

This foresightedness of WHO came to reality very soon, and the struggle became very real for the whole world, including the developed nations. During the early stages of this calamity, the world witnessed shortages of cures, preventive vaccines and disruptions in the production and supply of preventive diagnostics and therapeutics.[3] These unparalleled demands were for not just the supply of existing products and technology but also the then non-existent preventive drugs and vaccines.

These shortages were not limited to the underdeveloped or developing countries only. The developed countries also faced the brunt of it. In fact, several testing supplies and equipment are still on the Medical Device Shortage List of the US Food and Drug Administration.[4] But the scale and impact of the shortage and inaccessibility of medical supplies, personal protective equipment, and medicines were much worse for the underdeveloped and developing countries as compared to the developed ones.

The already existing socio-economic gap between the developed countries and the least developed nations multiplied once the vaccines were developed and approved for use across the world. This disparity between the two groups is clearly highlighted in the Global Dashboard for Vaccine Equity maintained by the United Nations Development Programme (UNDP).[5] UNDP's similar dashboards for vaccine access[6] and vaccine affordability[7] further substantiate the glaring disparity.

In view of the above-stated background and the prevailing public health conditions, India and South Africa began advocating for IP waiver to ensure that IPR protection does not act as a barrier to the prompt and efficient supply of IP-protected resources. In light of shortages of preventive products such as personal protective equipment and access to affordable medical products, including diagnostic kits and other medical resources, India and South Africa pitched for a re-evaluation of the IP regime during pandemic times. Consequently, on October 2, 2020, both countries jointly communicated a

[2]Ibid.
[3]https://www.pharmacytimes.com/view/newest-covid-19-surge-leads-to-shortages-in-therapeutics;https://www.who.int/news/item/25-02-2021-covid-19-oxygen-emergency-impacting-more-than-half-a-million-people-in-low--and-middle-income-countries-every-day-as-demand-surges; accessed on 01.02.2023.
[4]https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list#shortage as on 26.04.2024; accessed on 12.06.2024.
[5]UNDP: United Nations Development Programme.
[6]https://data.undp.org/vaccine-equity/accessibility/; accessed on 05.04.2023.
[7]https://data.undp.org/vaccine-equity/affordability/; accessed on 05.04.2023.

proposal to the WTO that, in their understanding, could resolve the glaring issues the world population was facing.[8]

THE PROPOSAL - INITIAL

The concern regarding the inaccessibility of resources in relation to COVID-19 therapeutics, diagnostics, and vaccines was communicated by India and South Africa[9] to the Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as TRIPs) Council on October 2, 2020, via their joint proposal for waiver from certain provisions of the TRIPs Agreement for the prevention, containment, and treatment of COVID-19 (hereinafter referred to as "The Initial Proposal").[10] India and South Africa advocated that IP rights hinder the timely provision of affordable medical products to patients.[11]

The requests made in the initial proposal included that the TRIPs Council recommend to the General Council *"a waiver from the implementation, application and enforcement of Copyrights and Related Rights, Industrial Design, Patents and Protection of Undisclosed Information covered under certain provisions of the TRIPs Agreement*[12] *in relation to prevention, containment or treatment of COVID-19"*[13]*,* wherein the waiver should continue till the "*widespread vaccination is in place globally"*.[14]

India and South Africa's initial proposal on IP waiver, though supported by 100 countries, was strongly opposed by a number of countries, including the United Kingdom, the United States, Japan, Canada, Brazil, Australia, Norway, Switzerland, and the European Union, at a WTO's meeting on November 20, 2020.[15]

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[8]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

[9]Additionally, on 23rd November 2020, South Africa presented to the TRIPs Council a communication that contained detailed examples of IP Issues and barriers in COVID-19 Pandemic. South Africa maintained that IP exclusivity restricted manufacturing and supply alternatives that could lower drug prices and facilitate efficient access. This document dealt with the problem related to the shortage of therapeutics but also explored as to how the Patent Landscape would be shaped during the pandemic times. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W670.pdf&Open=True; accessed on 24.04.2023.

[10]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

[11]Ibid.

[12]https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.

[13]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

[14]Ibid.

[15]https://www.theeastafrican.co.ke/tea/science-health/Covid-vaccine-patent-rights-3214866; accessed on 05.04.2023.

THE PROPOSAL - REVISED

After several rounds of discussions and deliberation on the comments received on the initial proposal's decision text, a large group of countries, including India and South Africa, circulated the *revised decision text* titled '*Waiver from certain provisions of the TRIPs Agreement for the prevention, containment, and treatment of COVID-19*' (hereinafter referred to as the 'Revised Proposal') to the TRIPs Council on May 25, 2021.[16]

The revised proposal put forth the suggestion that certain provisions of the TRIPs Agreement be waived in relation to health products and technologies, including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment, or containment of COVID-19.[17]

The revised proposal restricted the scope of the proposed waiver in relation to health products and technologies only (including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment, or containment of COVID-19). The same was in contrast to the initial proposal's wider scope which covered copyrights, industrial designs, patents and undisclosed information in relation to the prevention, containment, or treatment of COVID-19. The revised proposal presented a more acute and narrow scope of the proposed waiver as compared to the initial proposal. Further, the revised proposal also included that the waiver be in force for at least 3 years from the date of the decision and be open to review thereafter.[18]

OPPOSITIONS / SUPPORT TO THE REVISED PROPOSAL

The revised proposal submitted to the TRIPs Council was opposed by several countries, including the European Union, Canada, Germany[19], Japan, Australia, and the United Kingdom.[20] Countries such as the United States of

[16]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True; accessed on 05.04.2023.
[17]Ibid; Page 3 of the Revised proposal; accessed on 05.04.2023 WTO also received petitions from non-governmental organizations such as the online activist networks and others in favour of access of affordable COVID-19 vaccines across the globe. https://www.wto.org/english/news_e/news21_e/covid_07jun21_e.htm; accessed on 24.04.2023.
[18]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True; Page 3 of the Revised proposal; accessed on 05.04.2023.
[19]https://www.euronews.com/2021/05/06/us-backs-waiver-on-intellectual-property-rights-for-covid-19-vaccines; accessed on 13.04.2023 and The Office of the then German Chancellor, Angela Merkel, on 6th May, 2021, in its statement stated that *"the protection of intellectual property is a source of innovation and must remain so."*
[20]https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf; https://www.theeastafrican.co.ke/tea/science-health/covid-vaccine-patent-rights-3214866.

America (USA)[21] and France[22] on the other hand, announced their support for the waiver in May 2021.

The countries opposing the IP waiver advocated that the IP protection encourages innovation[23] and facilitates the production of vaccines. They argued that IP was an incentive in the process of vaccine generation and would help in combating the variants of coronavirus.[24] These countries also maintained that voluntary licensing of vaccines, a provision already available to the manufacturers of the vaccines, could be employed to effectively counter the increasing menace of COVID-19.[25]

The United Kingdom and the European Union advocated that the IP played a positive role in managing the response to the pandemic,[26] in generating vaccines against COVID-19 and in providing an incentive to encourage work on new variants of the SAR-COV-2 virus. United Kingdom and European Union, instead of patent waiver, thus recommended voluntary licensing of vaccines.[27]

On June 18, 2021, the European Union submitted to the TRIPs Council that Member States should employ provisions such as compulsory licensing enshrined in the TRIPs Agreement instead of resorting to patent waiver.[28] They encouraged Member States to undertake international joint initiatives to facilitate equitable access to vaccines or medicines.[29]

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[21]https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver; accessed on 13.03.2023.

[22]https://www.france24.com/en/france/20210506-france-expands-vaccine-program-as-macron-voices-support-for-patent-waiver; accessed on 13.04.2023.

[23]https://www.bbc.com/news/world-europe-57013096; accessed on 13.04.2023.

[24]https://www.gov.uk/government/speeches/world-trade-organization-general-council-november-2021-uk-statements?utm_source=HOC+Library+-+Current+awareness+bulletins&utm_campaign=d40063d6ac-Current_Awareness_IADS_25_11_2021&utm_medium=email&utm_term=0_f325cdbfdc-d40063d6ac-103780026&mc_cid=d40063d6ac&mc_eid=ec2ad28b66; accessed on 14.04.2023.

[25]Ibid.

[26]https://www.gov.uk/government/speeches/world-trade-organization-general-council-november-2021-uk-statements?utm_source=HOC+Library+-+Current+awareness+bulletins&utm_campaign=d40063d6ac-Current_Awareness_IADS_25_11_2021&utm_medium=email&utm_term=0_f325cdbfdc-d40063d6ac-103780026&mc_cid=d40063d6ac&mc_eid=ec2ad28b66; accessed on 14.04.2023.

[27]https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf; accessed on 14.04.2023.

[28]In communication titled *'Draft General Council Declaration on the TRIPs Agreement and Public Health in the Circumstances of a Pandemic'* https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W681.pdf&Open=True; accessed on 24.04.2023.

[29]Ibid.

Keeping in view the numerous reservations posed by several countries across the globe,[30] the WTO announced a compromise text in June 2022 (hereinafter referred to as the WTO Proposal). This WTO proposal was narrower in scope than the earlier proposals submitted by India and South Africa.

THE MINISTERIAL DECISION

After a trail of discussions, meetings, and several negotiations spanning about a year and a half, the WTO Proposal, titled Draft Ministerial Decision on TRIPs Agreement, was introduced during the 12th Session of the Ministerial Conference in Geneva (from June 12 – 15, 2022).[31] This proposal was adopted by all the members on June 17, 2022, as the 'Ministerial Decision'.[32]

Relying on the 'Doha Declaration on the TRIPs Agreement and Public Health' 2001,[33] the WTO Member States agreed that the TRIPs Agreement should not prevent the Member States from undertaking measures to protect public health. Accordingly, through the Ministerial Decision, a waiver of certain provisions of Article 31 of the TRIPs Agreement was adopted.

Article 31 of TRIPs deals with the use of the subject matter of a patent without the authorization of the right holder. In light of the above, the Ministerial Decision allowed for the implementation of the following flexibilities with respect to the subject matter of the patent required for the production and supply of COVID-19 vaccines:

- It allowed eligible Members[34] to use the subject matter of the patent[35] for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the pandemic for a period of five years.[36]

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[30]Also see https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W673.pdf&Open=True; accessed on 14.04.2023.

[31]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True

[32]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True

[33]https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf; https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm accessed on 24.04.2023.

[34]Eligible Members are defined as all developing country Members.

[35]'Subject matter of a patent' includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine. https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True

[36]Ibid. The time period of 5 years may be extended due to the exceptional circumstances of the Covid-19 pandemic. Further, this Ministerial decision further states that the Developing country Members with existing capacity to manufacture Covid-19 vaccines are encouraged to make a binding commitment not to avail themselves of

- An eligible member may authorize use of the subject matter of a patent without the right holder's consent through any instrument available under the laws of the member (whether or not a member has a compulsory license regime in place).
- Members are to decide within six months whether they will extend the provisions of the decision to cover the production and supply of COVID-19 diagnostics and therapeutics.[37]
- A member may also allow the products manufactured to be exported to eligible members, subject to certain exceptions. However, eligible members must take reasonable efforts to prevent the re-exportation of the products.
- Members must also ensure that there are effective measures in their territory to prevent the import and sale of manufactured products.
- The determination of adequate remuneration for the right holder may take into account the humanitarian and not-for-profit purposes of the vaccine distribution programs.[38]

Additionally, it was also decided that the provisions of the Ministerial Decision may be applied by an eligible member until 5 years from the date of the said decision. It was also set to be reviewed by the General Council for TRIPs every year. The adeptness and need of the Ministerial Decision can be understood by referring to the statistics available with respect to several aspects of the pandemic. As of May 26, 2024, there have been approximately 77,55,79,926 confirmed cases of Covid-19 and 70,50,567 deaths globally.[39]

As stated in one of the preceding paragraph, the Members were to decide the extension of the Ministerial Decision to cover the production and supply of COVID-19 diagnostics and therapeutics within 6 months. On December 19-20, 2022, this deadline was extended by the General Council of TRIPs on the recommendation of the TRIPs Council.[40] During the meeting of the TRIPs Council on March 16-17, 2023, the question of covering the production and supply of Covid-19 diagnostics and therapeutics was discussed further but no decision was reached. The 13th Ministerial Conference of the WTO which concluded on March 1, 2024, also failed to reach an agreement for the extension of the IP waiver to diagnostics and therapeutics.[41]

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this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10th May 2022.

[37]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True

[38]Ibid.

[39]https://data.who.int/dashboards/covid19/cases?n=c, https://data.who.int/dashboards/covid19/deaths?n=c.

[40]https://www.wto.org/english/news_e/news22_e/dgno_20dec22_e.htm.

[41]https://bio.news/international/wto-ministerial-covid-ip-intellectual-property-waiver-diagnostics-therapeutics/

INITIAL & REVISED PROPOSAL VS. FINAL DECISION

The initial and revised proposal referred to the waiver of IP rights with respect to copyrights, industrial designs, patents and undisclosed information, whereas the Ministerial Decision covered the waiver of IP rights in connection with patents only.

Further, the initial as well as the revised proposal proposed waivers in relation to health products and technologies, including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment, or containment of COVID-19 whereas the Ministerial Decision covered only the subject matter of the patent required for the production and supply of COVID-19 vaccines. The decision regarding extension of waiver to therapeutics and diagnostics remains undecided till the date of submission of this article for publication, that is, 12th June, 2024.

AFTER THE MINISTERIAL DECISION

In November 2022 (after the Ministerial Decision), WHO released a report titled "Global Vaccine Market Report."[42] The report highlighted the inequitable distribution of COVID-19 vaccines. It was stated that even though the African region represents 1/5th of the global population, the region received only 3% of all COVID-19 vaccine doses[43] in 2021. Thus, access to vaccines remains limited for lower-income countries. Though the inequity was not unique to COVID-19 situation, it was unprecedented due to the scale of the pandemic itself.[44]

It was also stated in the report that *"... access to life-saving innovations such as vaccines were not available to all who need them in a timely and equitable manner, including because of intellectual property monopolies. In addition to the effect on pricing, intellectual property continues to limit the possibility of leveraging fully the capacity to produce and supply locally and regionally in lower-income countries."*[45] The report called upon the pharmaceutical industry as well as governments to take steps to establish provisions for technology transfer to ensure equity-driven allocation of products.[46]

CONCLUSION

COVID-19 impacted not only public health but had severe implications for the economies of most nations. One of the main objectives behind the TRIPs

[42]https://www.who.int/publications/m/item/global-vaccine-market-report-2022.
[43]Ibid; Page 16 of the Report.
[44]Ibid; Page 16 of the Report.
[45]Ibid; Page 17 of the Report.
[46]Ibid; Pages 21-22 of the Report.

waiver was to ensure that IP does not became a barrier to public health in low and middle income nations. There were concerns that the third world countries would not be able to secure enough vaccine doses for their population and thus the goal for the Ministerial decision was to address global inequalities and ensure equitable access to vaccines and medicines to combat the pandemic globally. While the developing and least developed nation have been contending that the concentration of manufacturing contributes to the inequitable rollout of COVID-19 diagnostics and therapeutics, the developed nations question whether intellectual property is the cause of the access problem.[47]

The 'Patent-related waiver for COVID-19 vaccines production and supply' does not seem to have a significant impact on the equal access and distribution of vaccines. Even though the vaccines for COVID-19 were the fastest developed vaccines in the history of mankind, worldwide access to these vaccines was uneven. As of June 11, 2024, only 32.8% of people in low-income countries have received at least one dose.[48] This data elaborates that IP is not a barrier considering the waiver did not seem to be of much value in providing the equitable access to vaccines. Also, the Ministerial decision on Patent waiver did not seem to have any meaningful impact on the equitable access to vaccines, at least on the stand-alone basis.

Further, while equal distribution of COVID vaccine, therapeutics and diagnostics to combat COVID is essential, it is also important to maintain an equilibrium between the rights of IP holders and public health. IP protection incentivizes and encourages IP creation. In the absence of monetary benefits and the exclusivity IP regimes provide, innovation in society, especially in times of crisis, is likely to be affected on a large scale.

The author is of the opinion that the patent waiver as provided under the Ministerial Decision, coupled with the technology transfer, compulsory licensing and voluntary licensing may play a pivotal role in addressing the deadly effects of the pandemic. Thus, the combination of these flexibilities available under the TRIPs and the Ministerial Decision should be used to maintain public health.

It may be kept in mind that in order to protect their citizens and economies from the detrimental aftermath of COVID-19 pandemic, the requirements of developed countries, developing countries, and least developed nations may differ from each other. A straight-jacket formula will not be a reasonable response to bring countries on par with each other when they're at different socio-economic levels.

[47]https://www.wto.org/english/thewto_e/minist_e/mc13_e/briefing_notes_e/trips_e.htm

[48]https://ourworldindata.org/covid-vaccinations