



WTO TRIPs | Waiver on COVID-19 vaccines: Promoting One World, One Health

After the outbreak of new COVID-19 variants, which are more infectious and deadly, the world saw a catastrophic impact on the developing countries like India. We witnessed the most unfortunate sight of people suffering due to inadequate supply of oxygen, ventilators, beds, medical staff and other medical equipment. Collapsing healthcare system brought out the vulnerabilities of low- and middle-income countries to this pandemic.

The current situation has intensified scary prospects of future waves of the COVID and the only resort is vaccination. Despite eight vaccines around the world in the market in less than one year of the COVID-19 pandemic outbreak, India is facing shortages and inequitable distribution of the vaccines.

At least five billion people need to be vaccinated to control the current situation and prevent the outbreak of future waves for which India requires 10 billion doses of vaccines. With limited capacity of producing 3.5 billion doses low- and middle-income countries are experiencing inadequate access to vaccines as at the current capacity the developed countries have secured most of their production.

In this context, the debate initiated by India and South Africa through their joint proposal to grant a temporary waiver to the specific provisions of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) has been supported by more than 100 other members of the WTO including the US.

Furthermore, stressing on the need for unity and solidarity during this global health crisis, Indian Prime Minister Narendra Modi has sought support for text-based negotiation from the G-7 nations at their Summit in Cornwall, United Kingdom, which was held from 11th to 13th June, 2021.

India has suggested to other WTO members to begin text-based negotiations from mid-June on the temporary TRIPs waiver proposal to deal with the COVID-19 pandemic, as there is no time to lose and countries should look at concluding the talks by July-end.

Since the statement supporting this call by the US Trade Representative (USTR), 62 countries sponsoring a TRIPs waiver have submitted a revised proposal to advance text-based negotiations. Importantly, while the US and China are open to negotiating TRIPs waiver, Germany has opposed it, while the EU has urged a ‘third way proposal’.

The TRIPs waiver, if in place, ensures transfer of technological know-how, rapid scaling-up of manufacturing of vaccines and medical products to fight the COVID-19 pandemic and ensure easy access to vaccines.

However, many pharmaceutical companies are wary that with the TRIPs waiver multiple manufacturers can start producing vaccines. They anticipate that most countries do not have adequate manufacturing capacity to produce vaccines. Hence, apprehension is that a waiver could impact patient safety by opening doors for counterfeit vaccines to enter the supply chains.

In this background, this Occasional News Wrap (ONW) captures various views expressed on this subject. This is a third volume of CUTS ONW on this subject, which covers various dimensions of TRIPs waiver on the COVID-19 vaccines so that they are available in an affordable manner worldwide, including the least developed countries.

This ONW is categorised into four sections, which are as follows:

1. US and Others Support TRIPs Waiver
2. Indemnity Clause and Commencement of Text-based Negotiations
3. Technology Transfer and Scaling Up for Equitable Access to Vaccines
4. Apprehensions and Warnings

US and Others Support TRIPs Waiver

<p>1.</p> <p>After US backs joint WTO proposal with S Africa: India hopeful of more support for Covid-19 vaccine IP waiver</p> <p><i>By Kirtika Suneja</i></p> <p>The Economic Times May 07, 2021</p>	<p>After gaining US backing, India is hopeful of more countries supporting its joint proposal with South Africa at the World Trade Organisation (WTO) to waive intellectual property rights or patent protection on COVID-19 vaccines. Such a move could potentially lead to an increase in vaccine output and availability as India battles a record pandemic surge.</p> <p>The European Union, which had earlier opposed the proposal, is ready to discuss the matter; French President Emmanuel Macron said he was “absolutely in favour”. Canada indicated backing while New Zealand said it strongly supported a TRIPs waiver.</p>
<p>2.</p> <p>Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic</p> <p>World Trade Organisation May 12, 2021</p>	<p>Bolivia notified the WTO it needed to import 15 million doses of a vaccine under the legal system introduced in a 2017 amendment to the TRIPs Agreement. That amendment, which created Article 31bis of the TRIPs Agreement, provides an additional legal pathway for import-reliant countries to access affordable medicines, vaccines and other pharmaceutical products.</p> <p>Bolivia's submission follows through on its February notification signalling that it intended to exercise the flexibilities under the amendment.</p>
<p>3.</p> <p>India and US discuss revised proposal for TRIPs vaccine waiver</p> <p><i>By Dipanjan Roy Chaudhury</i></p> <p>The Economic Times May 16, 2021</p>	<p>USTR Katherine Tai has expressed her country’s support for India’s revised proposal for a waiver to certain intellectual property protections for COVID-19 vaccines in a virtual meeting with Commerce and Industry Minister Piyush Goyal.</p> <p>Tai welcomed an update from Goyal about India’s efforts to revise and resubmit the proposal for a waiver to certain provisions of the WTO Agreement on TRIPs to ensure people across the world are vaccinated against the COVID at the earliest.</p>
<p>4.</p> <p>China supports IP rights waiver on COVID-19 vaccines: Foreign Ministry</p> <p><i>By Sutirtho Patranobis</i></p> <p>Hindustan Times May 17, 2021</p>	<p>China said it supports appeals made by developing countries for waiving IPRs for COVID-19 vaccines as questions are raised on the equitable distribution of the shots globally.</p> <p>Foreign Ministry spokesperson, Zhao Lijian said as the largest developing country, China supports the appeal to waive IPRs as long as it is conducive to the inoculation needs of developing countries.</p> <p>China fully understands and supports the request of developing countries to exempt the IPRs of COVID-19 vaccines, Zhao said.</p>

<p>5.</p>	<p>A patent waiver on COVID vaccines is right and fair Nature May 25, 2021</p>	<p>At present, the proposal does not have the support of the pharmaceutical industry, nor that of most high-income nations. Instead, these countries are pledging to share more of their own vaccines with low-income nations and to provide more funding to charitable vaccine-provision schemes such as COVAX.</p> <p>However, in a surprising and welcome move, the US, Russia and China came out in support of an IP waiver on vaccines.</p>
<p>6.</p>	<p>BRICS backs India-South Africa's COVID-19 vaccine patent waiver proposal Economic Times June 01, 2021</p>	<p>BRICS extended their support for a temporary global waiver on patent protection for COVID-19 vaccines and also reiterated the need for sharing of vaccine doses, transfer of technology, development of local production capacities and supply chains for medical products.</p> <p>The foreign ministers of BRICS (Brazil, Russia, India, China and South Africa) held a meeting and stressed the need to promote initiatives aimed at ensuring timely, affordable, and equitable access to, as well as the distribution of diagnostics, therapeutics, medicines and vaccines.</p>
<p>7.</p>	<p>India gets wide support on TRIPs waiver for COVID-19 vaccines at G-7 meet By <i>Shreya Nandi</i> Business Standard June 14, 2021</p>	<p>The Prime Minister also found widespread support from leaders, including the Australian Prime Minister, the Director General of the WTO, as well as the UN Secretary General, for text-based negotiations for a temporary patent waiver for COVID-19 vaccines, proposed by India and South Africa at the WTO.</p>
<p>8.</p>	<p>Modi seeks support of G-7 Nations for TRIPs Waiver at WTO The Hindu Business Line June 13, 2021</p>	<p>Stresses on need for global unit, leadership, solidarity to prevent future pandemics.</p> <p>Prime Minister Narendra Modi sought the support of G-7 nations for the proposal moved by India and South Africa at the WTO for temporarily waiving some TRIPs provisions for COVID-19 related vaccines and medical products.</p>
<p>Indemnity Clause and Commencement of Text-based Negotiations</p>		
<p>9.</p>	<p>Foreign Vaccines Like Pfizer, Moderna A Step Closer With Key India Waiver NDTV June 02, 2021</p>	<p>In a big move to clear the way for foreign vaccines like Pfizer and Moderna, the drug regulator has done away with the requirement of India-specific trials. Foreign vaccines approved by specific countries and WHO for emergency use will no longer need bridging trials in India, the Drug Controller General of India (DCGI) has said in an attempt to fast-track the import of doses needed to bolster vaccinations.</p> <p>Pfizer and Moderna were among the companies that had requested the government for waivers like indemnity and for</p>

		<p>post-approval local trials. The government has yet to take a decision on indemnity or liability from compensation for any severe side effects.</p>
10.	<p>Explainer: What the indemnity clause is and how its waiver will accelerate COVID-19 vaccine process in India</p> <p>Firstpost June 04, 2021</p>	<p>Vaccine manufacturers Moderna and Pfizer are ready to supply their COVID-19 vaccines to India provided the Government of India gives them indemnity against any liabilities from the usage of their vaccines.</p> <p>The "indemnity clause" is reportedly one of the main reasons why the two vaccine manufacturers have stayed out of India despite a staggering shortage of vaccines in the country, and independent tenders being floated by several state governments across India.</p>
11.	<p>COVID-19: US vaccine sharing with India may hinge on indemnity waiver</p> <p><i>By Indrani Bagchi</i></p> <p>Times of India June 05, 2021</p>	<p>The 'vaccine sharing' initiative of the US, which will see the country giving 80 million doses of COVID-19 vaccines to countries around the world, might put India in a piquant position.</p> <p>The Biden administration clarified that the US would ship out 25 million doses immediately. About 75 per cent of the 80 million doses would be given over the summer month.</p>
12.	<p>WTO decides to hold text-based negotiations on India's global vaccine waiver proposal</p> <p><i>By Subhayan Chakraborty</i></p> <p>Money Control June 10, 2021</p>	<p>India's proposal to waive IPRs for COVID-19 vaccines, drugs and related health technology has been cleared for 'text-based discussions' at the WTO.</p> <p>The WTO Council on TRIPs passed the proposal on June 09, 2021 thereby opening it up to further debate by all members. India's updated draft of its proposed IPR waiver, sponsored by 62 nations, was submitted to the WTO on May 21, 2021 and discussed by the TRIPs Council on May 30, 2021.</p>
13.	<p>WTO members agree to talks on patent waiver for COVID drugs, vaccines</p> <p>Times of India June 10, 2021</p>	<p>WTO Members agreed to launch discussions on patent waiver for COVID-related vaccines, drugs and devices, amid indications that the talks will be fast-tracked. At a meeting of a key WTO panel looking into the issue, India suggested that detailed deliberations should begin next week with an intent to clinch a deal by the end of July. Although the European Union, the UK and Switzerland reiterated their opposition, they agreed to join text-based talks, for which a draft has been shared.</p>
14.	<p>India asks WTO members to finish TRIPs waiver on COVID-19 vaccines talks by July-end</p> <p>Business Today June 10, 2021</p>	<p>India has suggested to the WTO members to begin text-based negotiations from mid-June on the temporary TRIPs waiver proposal to deal with the COVID-19 pandemic, as there is no time to lose and countries should look at concluding the talks by July-end.</p>

		The country would also like to enter into line-by-line negotiations on the text and it is open and flexible to engage in all possible formats, whether, in plenary or small group meetings, India said in a statement on TRIPs waiver proposal in the formal TRIPs Council Meeting held in Geneva on June 08-09, 2021.
Technology Transfer and Scaling Up for Equitable Access to Vaccines		
15.	Hoping for quick resolution on TRIPs waiver for Covid jabs at WTO: Goyal <i>By Shreya Nandi</i> Business Standard May 13, 2021	India is looking forward to multilateral support and a speedy resolution on its proposal on temporary intellectual property waiver on Covid-19 vaccines at the WTO, Union Commerce and Industry Minister Piyush Goyal said. Besides, there is a need for expeditious consensus building , transfer of technology and availability of the raw materials to quickly overcome the Covid-19 induced crisis. The minister also urged countries to share vaccines liberally with those who are in dire need of them.
16.	WTO chief says world needs to double or even triple vaccine production ANI News May 17, 2021	The world needs to boost the production of vaccines, doubling or even tripling it, Ngozi Okonjo-Iweala, WTO chief, said at the Paris Peace Forum. "We need to scale up manufacturing [of vaccines]. Right now the world is capable of manufacturing about 5 billion doses of all kinds of vaccines but now we need to double that - to 10-15 billion doses. And the point is that we do not have the manufacturing capacity to do this," she said.
17.	DG Okonjo-Iweala calls on WTO members to tackle vaccine inequity World Trade Organisation May 21, 2021	DG Okonjo-Iweala, who has described equitable access to COVID-19 vaccines, diagnostics and therapeutics as "the moral and economic issue of our time," told the Global Health Summit, co-hosted by the European Commission and the Italian G20 Presidency, that the pandemic had made clear that "policymakers need to think of preparedness, response, and resilience as one interconnected package".
18.	Thank India, South Africa for Their Initiative at WTO to Waive IP Protections for COVID-19 Products: WHO Chief News 18 May 24, 2021	WHO Chief Tedros Adhanom Ghebreyesus thanked India and South Africa for their initiative at the world body to temporarily waive some TRIPs) rules on COVID-19 products. In his opening remarks to the World Health Assembly, World Health Organisation Director-General Ghebreyesus called on nations to share doses through COVAX and underlined the need to scale-up manufacturing of COVID-19 vaccines.

<p>19.</p>	<p>Not Just TRIPS Waiver, But Transfer of Know-How Also Required <i>By Dr. Amar Patnaik</i> Financial Express May 25, 2021</p>	<p>Quick vaccination against COVID 19 is the only hope in ending the global pandemic which has claimed more than 3.4 million lives so far. A hindrance to mass production of vaccines is the intellectual property rights enjoyed by their manufacturers under the WTO's Trade-related Intellectual Property Rights (TRIPS) regime.</p> <p>Big pharma industries are not in favour of sharing the rights and know-how needed to produce vaccines, citing intellectual property pilferage concerns.</p>
<p>20.</p>	<p>Co-sponsors propose at least three year patent waiver for covid drugs, vaccines <i>By Asit Ranjan Mishra</i> Mint May 22, 2021</p>	<p>The proposal for a patent waiver to boost supplies of life-saving drugs and vaccines for COVID-19, pioneered by India and South Africa at the WTO, received a boost as 62 co-sponsors have proposed the temporary waiver to be in place for at least three years advocating a practical and flexible duration given the uncertainty regarding vaccine effectiveness for children and against new variants.</p>
<p>21.</p>	<p>G7 summit: India to bat for global vaccine waiver, funding for global effort <i>By Subhayan Chakraborty</i> Money Control June 10, 2021</p>	<p>The G7 summit in Cornwall, UK is set to see India push for greater access to vaccines and technology on behalf of the developing world and poorer nations. The three-day summit will see leaders of the seven-richest economies along with the EU top brass meeting physically for the first time since the outbreak of the COVID-19 pandemic.</p>
<p>Apprehensions and Warnings</p>		
<p>21.</p>	<p>OPPI warns against vaccine patent waiver Times of India May 12, 2021</p>	<p>Waiving of intellectual property (IP) rights (IPs) will neither lead to higher production of vaccines or their increased deployment to fight COVID, since that is not the barrier to ensure availability of vaccines in India, according to the Organisation of Pharmaceutical Producers (OPPI), a body representing pharma MNCs.</p>
<p>22.</p>	<p>Patent Waivers For COVID-19 Won't Speed Up Vaccine Supply <i>By Anoo Bhuyan</i> India Spend May 18, 2021</p>	<p>Sharing vaccine formulae for COVID-19 with developing countries will not help mitigate the global pandemic crisis as many of these countries did not have the capacity to manufacture COVID-19 vaccines adequately, Bill Gates, one of the world's leading billionaires and philanthropists, said.</p> <p>A few days later, the Bill and Melinda Gates Foundation, of which he is co-chair, issued a statement saying they support a "narrow intellectual property waiver for COVID-19 vaccines during the pandemic". The Gates Foundation has been involved with vaccine-development efforts since early into the COVID-19 pandemic.</p>

<p>23.</p>	<p>EU, UK Raise Doubts About COVID Vaccine Patent Waiver NDTV June 01, 2021</p>	<p>The EU, Britain and Japan continued to voice doubts at the WTO about a proposed intellectual property waiver on COVID-19 products such as vaccines, Proposals to initiate text-based discussions on an IP waiver, rather than more general talks, gained traction at an informal meeting of the WTO Agreement on TRIPs Council.</p>
<p>24.</p>	<p>World Bank opposes vaccine intellectual property waiver as WTO talks resume The Hindu June 09, 2021</p>	<p>World Bank President David Malpass said the bank does not support waiving IPRs for COVID-19 vaccines at the WTO out of concern that it would hamper innovation in the pharmaceuticals sector.</p> <p>His comments on the subject, made during a call with reporters on World Bank economic forecasts, came as WTO negotiations over the proposed waiver resumed in Geneva.</p>
<p>25.</p>	<p>COVID-19 vaccine patent waiver is "no silver bullet" - EU's Michel Reuters June 10, 2021</p>	<p>A proposed waiver of IPRs for COVID-19 vaccines and treatments is "no silver bullet", European Council president Charles Michel said, adding he expected the topic to feature at the G7 summit.</p>