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Issue Brief

WTO TRIPS Waiver and COVID-19 Vaccine Equity

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S*ummary*

In October 2020, India and South Africa had submitted a proposal to the WTO, suggesting a waiver for certain provisions of the TRIPS Agreement for the prevention, containment or treatment of COVID-19. Though the TRIPS Council members agreed to text-based negotiations, the latest developments show that discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. If agreed, the waiver will help India address the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.

In October 2020, India and South Africa had submitted a proposal to the World Trade Organization (WTO), suggesting a waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the “prevention, containment and treatment of COVID-19”. The proposal seeks the waiver of “the implementation, application, and enforcement of sections 1, 4, 5 and 7 of part II of the TRIPS agreement”, which are stipulations referring to copyright, industrial design, patents, and undisclosed information (trade secrets).¹ The proponents of the proposal argue that a waiver will enable timely and equitable access to affordable health products and technologies, including vaccines.

Though many member countries had supported and co-sponsored the proposal, a small but influential group of countries, mainly Australia, Canada, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US), opposed it. They argued that existing exceptions under the TRIPS Agreement are sufficient to address the concerns mentioned in the proposal. This resulted in sidelining of the waiver proposal for months. However, on 5 May 2021, the Joseph Biden administration announced its support for waiving intellectual property protections for COVID-19 vaccines.² It was a significant step towards breaking the seven-month gridlock, and led to many more countries modifying their position on the waiver proposal.

On 25 May 2021, the co-sponsors of the waiver proposal submitted a revised proposal that specified the scope of the waiver as applying to “health products and technologies” and also added a section on the proposed duration of the waiver, i.e., three years.³ At present, more than 100 countries, including the US and China support this proposal. The principal opponent of the waiver is the EU and in June 2021, it submitted an alternative proposal to the TRIPS Council, which requested to keep TRIPS’ provisions intact and focused on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.⁴ The EU proposal also stated

¹ **“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, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization, 2 October 2020.

² **“Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver”**, *Office of the United States Trade Representative*, Executive Office of the President, 5 May 2021.

³ **“Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19”**, Revised Decision Text, IP/C/W/669/Rev.1, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization, 25 May 2021.

⁴ **“Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property”**, Communication from the European Union to the Council for TRIPS, IP/C/W/680, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization, 4 June 2021.

that the TRIPS Agreement does not prevent countries from taking measures to protect public health.⁵

At the meeting of the TRIPS Council on 8–9 June 2021, the member states agreed to text-based negotiations focusing on two proposals tabled by members. The members also decided to hold a series of meetings till the end of July 2021 to take stock of the text-based negotiations. However, the latest developments show that the waiver discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. This brief discusses how TRIPS becomes a barrier to the equitable access of COVID-19 vaccines. It also examines how a waiver will help India in its fight against COVID-19 at home and abroad.

TRIPS and its Exceptions

TRIPS, a comprehensive multilateral agreement on Intellectual Property (IP), was an outcome of the Uruguay Round (1986–94) of negotiations of the General Agreement on Tariffs and Trade (GATT). The Agreement came into force on 1 January 1995 and offers a minimum standard of protection for Intellectual Property Rights (IPR).⁶ In WTO, IPR are divided into two main categories. First, copyright and related rights (Articles 9 to 14, Part II of the TRIPS Agreement). Second, industrial property that includes trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information (Articles 15 to 38, Part II of the TRIPS Agreement).⁷

Article IX.3 and IX.4 of the Marrakesh Agreement Establishing the WTO deals with TRIPS waivers. Article IX.3 says that in “exceptional circumstances” the Ministerial Conference may waive off an obligation imposed on WTO member countries.⁸ Such a decision requires the support of three-fourths of the WTO membership. According to Article IX.4, any waiver granted for more than one year will be reviewed by the

⁵ **“Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic”**, Communication from the European Union to the Council for TRIPS, IP/C/W/681, *Council for Trade-Related Aspects of Intellectual Property Rights*, World Trade Organization, 18 June 2021.

⁶ Intellectual Property Rights are the rights given to people over the creations of their minds and provide to the creator an exclusive right over the use of his/her creations for a certain period of time. See **“What are Intellectual Property Rights?”**, *World Trade Organization*.

⁷ **“Agreement on Trade-Related Aspects of Intellectual Property Rights”**, The TRIPS Agreement, *World Trade Organization*.

⁸ The term “exceptional circumstances” has not been defined anywhere in the Agreement. However, the 2001 Doha Declaration on Public Health stated that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.

Ministerial Conference. Based on the annual review, the Conference may extend, modify, or terminate the waiver.

The TRIPS Agreement provides some flexibility primarily in the form of compulsory licensing and research exceptions through Articles 30 and 31. While Article 30 permits WTO members to make limited exceptions to patent rights, Article 31 provides a detailed exception, provided certain conditions are met. Compulsory licensing is the process of granting a license by a government to use a patent without the patent holder's consent. Article 31 permits granting compulsory license under circumstances such as “national emergencies”, “other circumstances of extreme urgency”, “public noncommercial use”, or against “anti-competitive” practices.⁹

In addition to these original waivers, the Declaration on the TRIPS Agreement and Public Health, adopted at the 2001 Doha Ministerial Meeting, also recognises some exceptions, for instance, in situations of a public health emergency, member countries have the freedom to determine the grounds upon which compulsory licenses are granted. Similarly, under Article 66.1, the least developed countries (LDCs) are given waivers for implementing TRIPS on pharmaceuticals till 1 January 2033.

COVID-19 and TRIPS Waiver

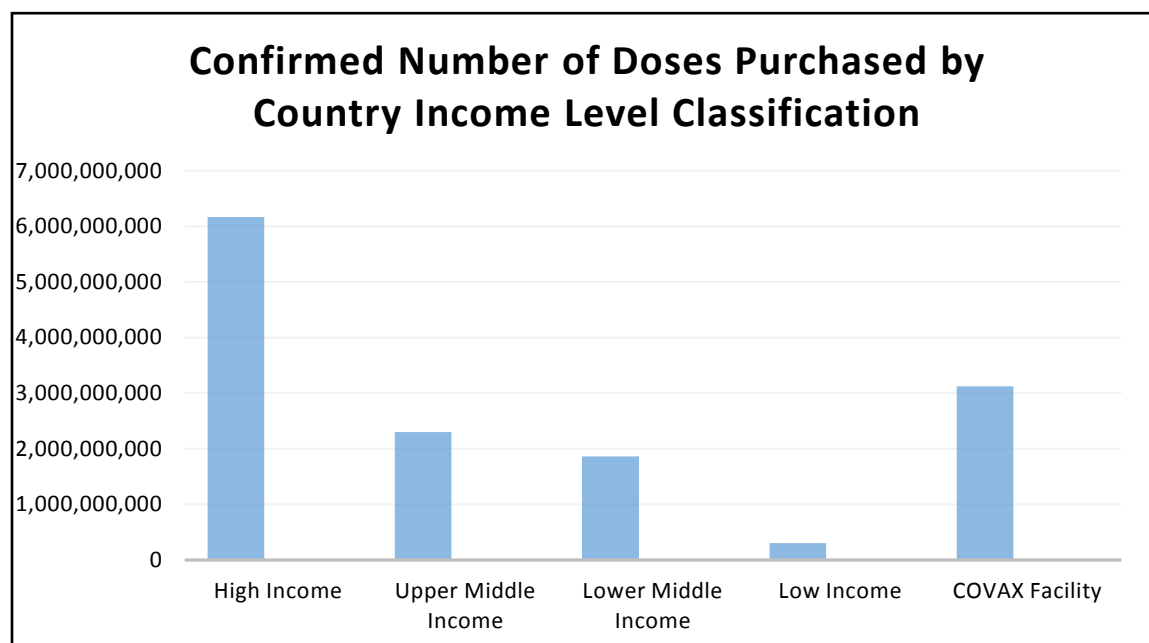
Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines.

Vaccine Inequity

According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of

⁹ “TRIPS and Pharmaceutical Patents: Obligations and Exceptions”, *World Trade Organization*, 2006,

the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.¹⁰ Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.¹¹



Source: [“Tracking COVID-19 Vaccine Purchases Across the Globe”](#), Duke Global Health Innovation Center, Updated 9 July 2021.

Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.¹² Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.¹³ South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per

¹⁰ [“Tracking Covid-19 Vaccine Purchases Across the Globe”](#), Launch and Scale Speedometer, Duke Global Health Innovation Center, Updated 9 July 2021.

¹¹ Ibid.

¹² [“More Than 3.33 Billion Shots Given: Covid-19 Tracker”](#), Bloomberg, Updated 9 July 2021.

¹³ [“Nine in 10 African countries set to miss urgent COVID-19 vaccination goal”](#), WHO Africa, 10 June 2021.

cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.¹⁴

This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world's population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution.

TRIPS: Barrier to Equitable Health Care Access

The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world's largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.¹⁵ The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.¹⁶

Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.¹⁷ Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla's decision to launch a generic version of cancer drug, "erlotinib". Though the Delhi High Court initially dismissed Roche's appeal

¹⁴ Kristalina Georgieva and Abebe Aemro Selassie, "**Sub-Saharan Africa: We Need to Act Now**", *IMF Blog*, 28 June 2021.

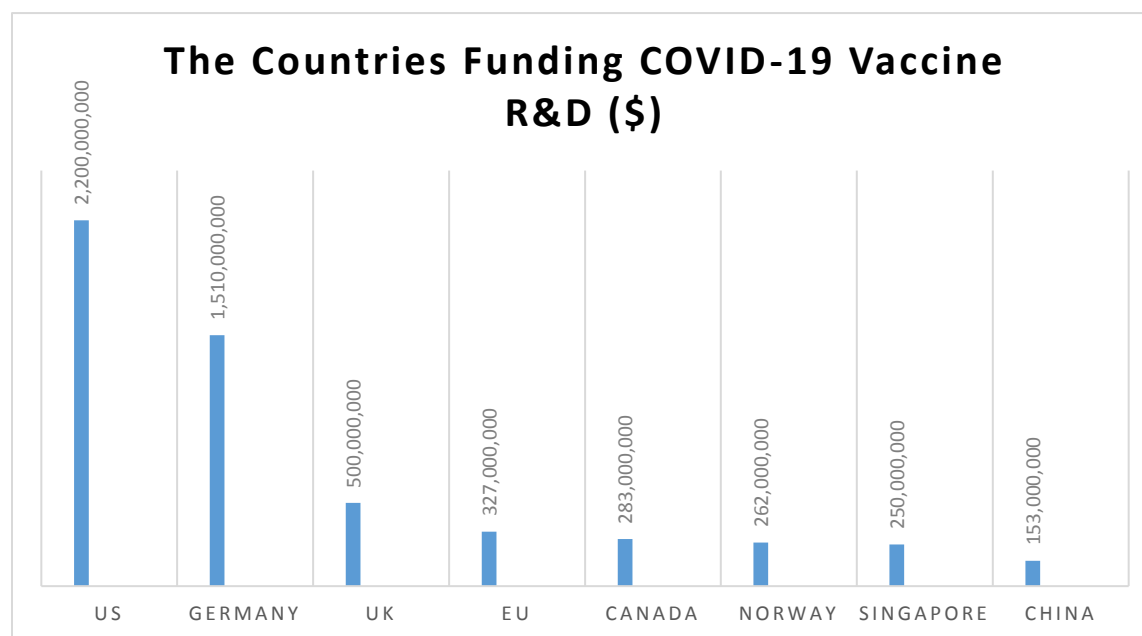
¹⁵ "**Medicines and Related Substances Control Amendment Act 90 of 1997**", *Government of South Africa*.

¹⁶ "**Pharmaceutical Company Lawsuit (Forty-two Applicants) Against the Government of South Africa (Ten Respondents)**", Notice of Motion in High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98, 18 February 1998.

¹⁷ "**Roche vs Indian Pharma: The Battle for a Cheaper Cancer Drug**", *The Economic Times*, 14 May 2017.

by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR.¹⁸ Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.¹⁹

A recent document by *Médecins Sans Frontières* (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.²⁰ The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.²¹



Source: “COVID-19 Vaccine R&D Investments”, *Global Health Centre*, Graduate Institute, Geneva, Updated 9 July 2021.

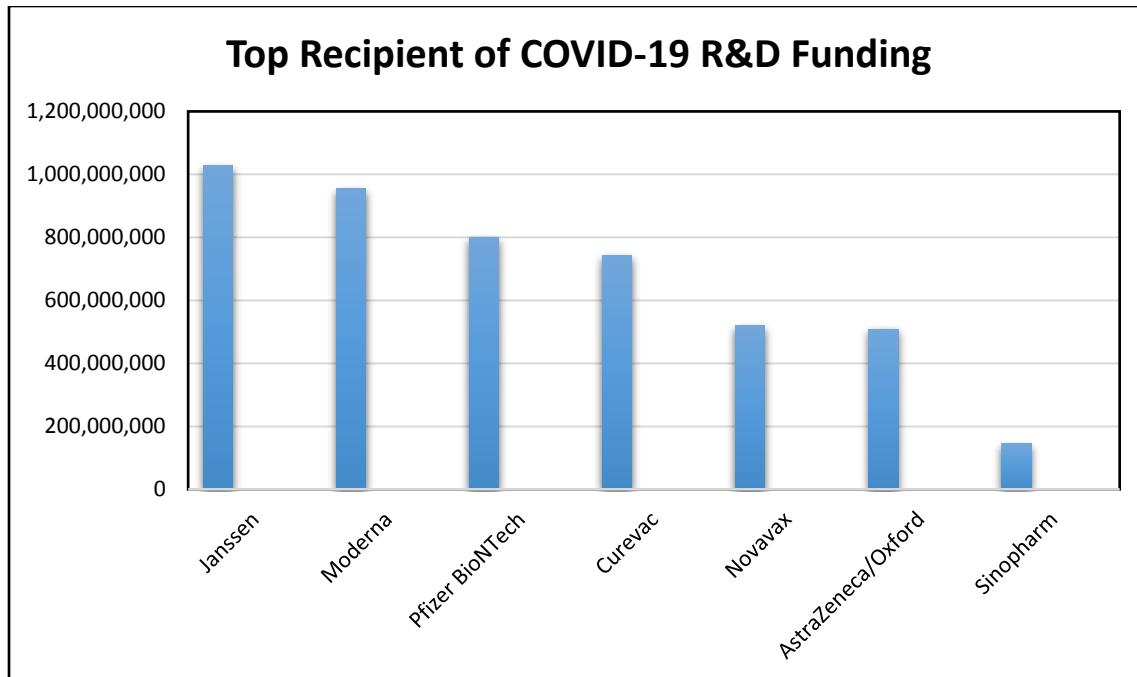
¹⁸ **“F. Hoffmann-La Roche Ltd. And Anr. Vs Cipla Limited”**, *High Court of Delhi*, 19 March 2008. The case was then taken to the Division Bench where it went in favour of Roche, see **“F. Hoffmann-La Roche Ltd. And Anr. Vs Cipla Limited”**, *High Court of Delhi*, 27 November 2015.

¹⁹ Lee Han-soo, **“Pfizer’s Patent Barrier Foils Korea’s 1st Pneumococcal Conjugate Vaccine”**, *Korea Biomedical Review*, 20 February 2019.

²⁰ **“India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-related Medical Technologies”**, Briefing Document, *Médecins Sans Frontières*, 18 November 2020.

²¹ **“A Fair Shot for Vaccine Affordability: Understanding and Addressing Effects of Patents on Access to Newer Vaccines”**, *Médecins Sans Frontières*, September 2017.

The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of \$6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.²² The US and Germany are the largest investors in vaccine R&D with \$2.2 billion and \$1.5 billion funding.



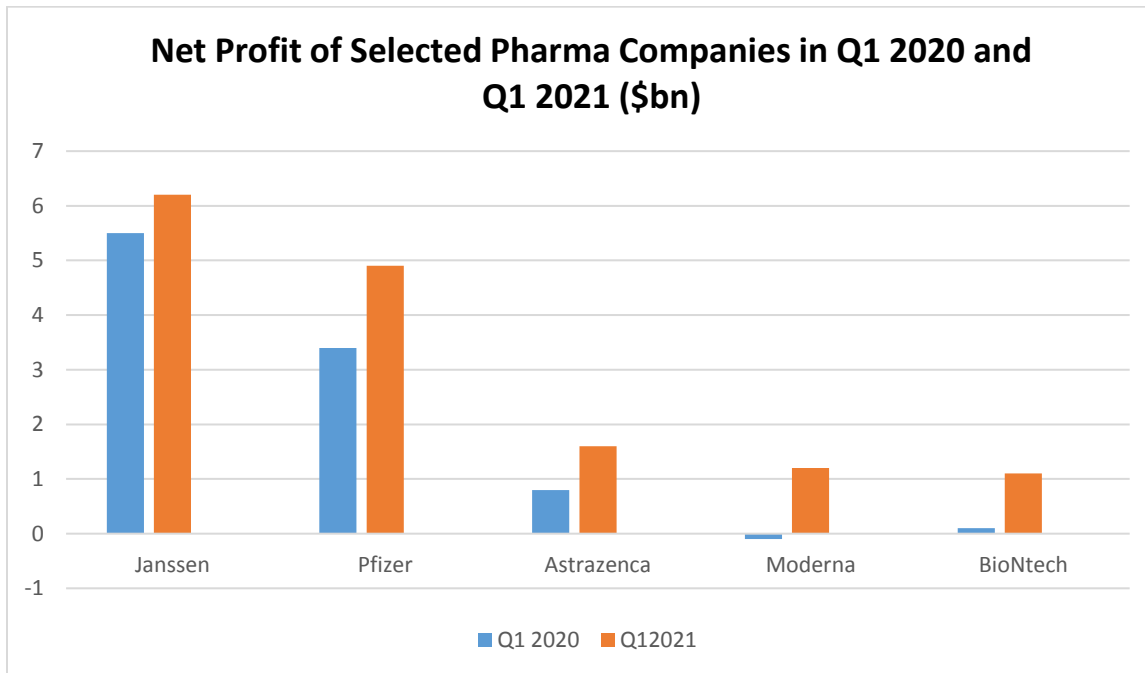
Source: “[COVID-19 Vaccine R&D Investments](#)”, *Global Health Centre, Graduate Institute, Geneva*, Updated 9 July 2021.

Private companies received 94.6 per cent of this funding; Moderna received the highest \$956.3 million and Janssen \$910.6 million. Moreover, governments also invested \$50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.²³ The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the

²² “[COVID-19 Vaccine R&D Investments](#)”, *Global Health Centre, Graduate Institute, Geneva*, Updated 9 July 2021.

²³ Ruchir Agarwal and Patrick Gaule, “[What Drives Innovation? Lessons from COVID-19 R&D](#)”, IMF Working Papers, *International Monetary Fund*, 19 February 2021.

scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines.



Source: Katharina Buchholz, [“COVID-19 Vaccines Lift Pharma Company Profits”](#), *Statista*, 17 May 2021.

One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."²⁴ Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries' products against this promise of technology transfer.

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors

²⁴ [“Uruguay Round Agreement: TRIPS, Part I—General Provisions and Basic Principles”](#), *World Trade Organization*.

contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines... And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”²⁵ Later, Shantha Biotechnics developed its own vaccine at \$1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally.

India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.²⁶ Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.²⁷ Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.²⁸ Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality

²⁵ Justin Chakma et al., **“Indian Vaccine Innovation: The Case of Shantha Biotechnics”**, *Globalization and Health*, Vol. 7, No. 9, 2011, p. 3.

²⁶ Biological E. has signed an agreement with Providence Therapeutics Holdings to manufacture its mRNA vaccine in India. The Pune-based Gennova Biopharma has also received necessary regulatory permissions to start the trials in the country for its mRNA vaccine.

²⁷ **“Special Press Conference to Mark the First Anniversary of the COVID-19 Technology Access Pool”**, *World Health Organization*, 28 May 2021.

²⁸ **“Việt Nam has COVID-19 Vaccine Production Capacity: Expert”**, *Việt Nam News*, 10 June 2021.

vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing.

Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

India's Role in Ensuring Vaccine Equity

India's response to COVID-19 at the global level was primarily two-fold. First, its proactive engagements in the regional and international platforms. Second, its policies and programmes to provide therapeutics and vaccines to the world. Since the beginning of the COVID-19 pandemic, India has been advocating international cooperation and policy coordination in fighting it. For instance, in April 2020, India co-sponsored a UN resolution that called for fair and equitable access to essential medical supplies and future vaccines to COVID-19. Later, in October 2020, India also put pressure on developed countries with a joint WTO proposal for TRIPS waiver.

India's *Vaccine Maitri* initiative also aims vaccine equity. As of 29 May 2021, India has supplied 663.698 lakh doses of COVID-19 vaccines to 95 countries. It includes 107.15 lakh doses as a gift to more than 45 countries, 357.92 lakh doses by commercial sales, and 198.628 lakh doses to the COVAX facility.²⁹ The COVAX initiative aims to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of their income level. India has decided to supply 10 million doses of the vaccine to Africa and one million to the UN health workers under the COVAX facility. India has also removed the IPR of Covaxin that would help platforms like C-TAP once WHO and developed countries' regulatory bodies approve the vaccine.

If agreed, the waiver would benefit India in many ways. First, more vaccines will help the country to control the pandemic and its recurring waves. Second, it will be a boost to India's pharma industry, particularly the generic medicine industry. According to the Biotechnology Innovation Organization, 834 unique active compounds are involved in

²⁹ **“Vaccine Supply”**, *Ministry of External Affairs*, Government of India, 29 May 2021.

the current R&D of COVID-19 therapeutics, vaccines, and diagnostics. It means that thousands of new patents are awaited, and that will hinder India's ability to produce COVID-19 related medical products. Only through a waiver, this challenge can be addressed.

Similarly, scientists note that mRNA is the future of vaccine technology. However, manufacturing mRNA vaccines involves complex processes and procedures. Only a very few Indian manufacturers have access to this technology; however, that too is limited. Once Indian companies have access to mRNA technology, it will help country's generic medicine industry and boost India's economy. Therefore, even if the WTO agrees on a waiver for a period shorter than proposed, India should accept it. In addition, mRNA vaccines can be produced in lesser time compared to the traditional vaccines. While traditional vaccines' production takes four to five months, mRNA needs only six to eight weeks. Access to this technology will be vital for India in expediting the fight against COVID-19 and future pandemics.

Finally, a waiver may strengthen India's diplomatic soft power. At present, what hinders India's *Vaccine Maitri* initiative is the scarcity of vaccines at home. On the other hand, China is increasing its standing in Africa, South America and the Pacific through vaccine diplomacy. The WHO approval of the Chinese vaccines and lack of access to vaccines by most developing countries, opens up huge space for China to do its vaccine diplomacy. Here, India should convince its Quad partners, particularly Australia and Japan, who oppose the waiver that vaccine production in developing countries through TRIPS waiver will enable the grouping to deliver its pledged billion doses of COVID-19 vaccine in the Indo-Pacific region.

In short, the proposed waiver, if agreed, will help India in addressing the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.

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