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The unwavering Covid-19 Vaccines' Intellectual Property rights Debate

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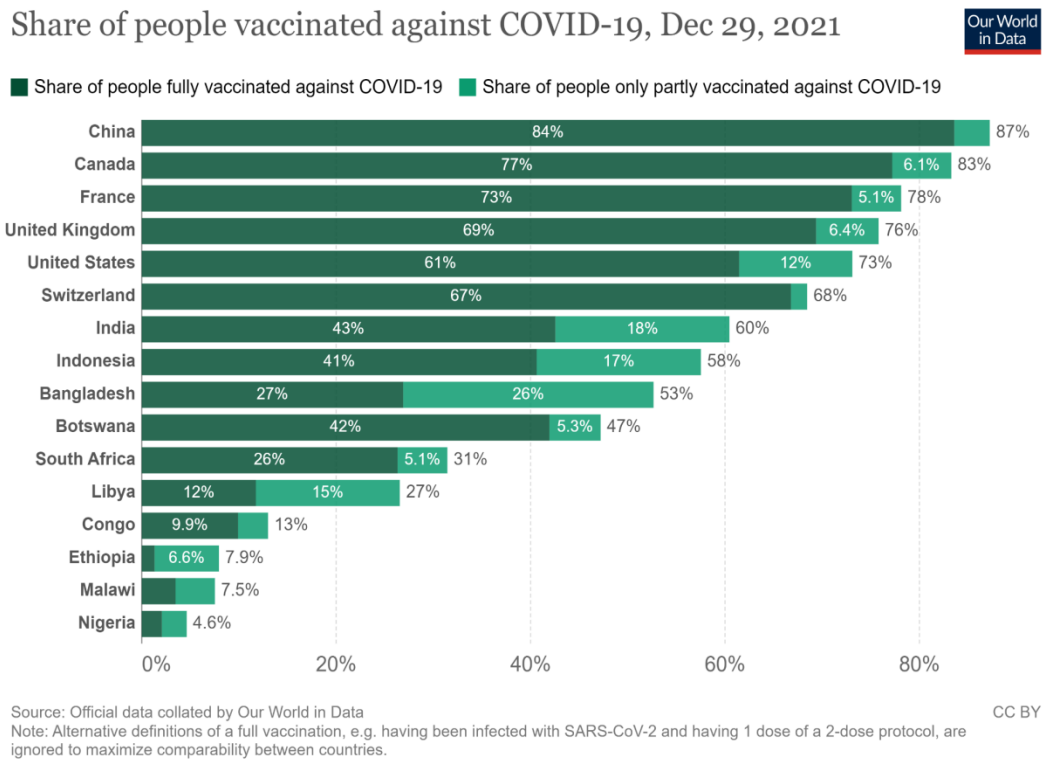
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With timely, effective vaccinations being the only somewhat successful cure for the virus, a frenzy to make, distribute, and dose people should become the world's priority, but it hasn't been as straightforward as one might assume. India and South Africa (underdeveloped and developing) submitted a request to the World Trade Organization (WTO) on the patent rights of Covid-19 vaccines on October 2, 2020. They have gotten unwavering backing from several other Member countries since then. They've suggested that several of the vaccine's intellectual property rights be waived. Until the World Health Organization proclaims COVID-19 herd immunity, this exemption would allow any country to produce the vaccine with more design and manufacturing freedom (WHO). Until the pandemic is completely contained, this would apply not only to vaccinations but also to diagnostics, medicines, and other technology. However, this stance has not been accepted by all and has sparked a debate over the intellectual property rights of the Covid-19 vaccine with the developed countries and pharmaceuticals opposing this move suggested by the developing and underdeveloped nations. They contend that there is little evidence that IPRs are impeding the development and spread of COVID-19 vaccines and treatments. Waiving all IPRs associated with COVID-19 before such proof is established looks unnecessary and may be harmful. This paper attempts to explore and analyze both key stances and draw out possible solutions for this current dilemma which is keeping the world on its toes.

Keywords: *patent rights, developing, developed countries, pharmaceuticals.*

INTRODUCTION

With its unforgiving nature and relentless approach, the Covid-19 virus along with a pandemic has also brought in a much-needed focus on the health care systems around the world and with timely, effective vaccines being the only partly effective solution for the virus, a frenzy to manufacture, distribute and dose people should become the priority of the world, however, this hasn't been as easy one would hope it would be. With data pouring in from all across the world with regards to the vaccine, compiling it and getting an overview provides a much-needed view to ascertain the alarming need for immunization.



Developed nations like the United Kingdom, France, and Switzerland have shown impressive results with close to 80% of the population vaccinated. Developing countries like India, Indonesia, and Bangladesh have had slower progress with approximately only 60% of the population having received their dosages. The worst-hit has been the underdeveloped

countries namely Congo, South Africa, Malawi, and Nigeria.¹ If the COVID-19 pandemic has shown us anything, it's that equitable vaccine availability is critical to global recovery. However, making this a reality necessitates the acquisition of resources, equipment, and, most critically, the ability to manufacture the vaccine in sufficient quantities to meet domestic demand. So, where do intellectual property rights come into play with manufacturing and distributing vaccine doses? Many have claimed that the trouble with sufficient vaccine supply presently isn't a lack of vaccine alternatives or even theoretical production capacity; it's the intellectual property (IP) protection that governs vaccine production and access—and, ultimately, the political and moral will to forfeit these protections in the face of a global crisis. Without this freedom, there will be insufficient vaccines to prevent the spread of variations, preventable deaths, and the continuous choking of low and middle-income countries (LMICs) by bad health. The major key players that have taken several stances include rich, developed countries; pharmaceuticals; and developing and underdeveloped countries who have been tussling over whether a waiver of the intellectual property rights must take place or not. With India and South Africa (developing and underdeveloped countries) having put the proposal before the World Trade Organization (WTO) a year ago to waive the patent rights under Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement², they have had to deal with alleged disagreement and contention from countries led by the European Union (EU) like the United Kingdom and Switzerland (rich, developed countries)³.

A similar standpoint taken to that of the EU countries is that of pharmaceuticals, specifically by the political advocacy group PhRMA, which represents over 30 pharmaceutical companies and has publicly expressed their dissent over President Biden's recent decision to back the 80

¹ 'Coronavirus (COVID-19) Vaccinations' (*Our World in Data*) <<https://ourworldindata.org/covid-vaccinations>> accessed 30 December 2021

² 'Waiver from Certain Provision of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' (*World Trade Organization*, 2 October 2020) <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>> accessed 31 December 2021

³ Philip Blenkinsop, 'Rich, developing nations wrangle over COVID vaccine patents' (*Reuters*, 10 March 2021) <<https://www.reuters.com/article/us-health-coronavirus-wto-idUSKBN2B21V9>> accessed 31 December 2021

countries pushing for a waiver of the patent rights.⁴ This article aims to highlight the key features of the TRIPS agreement that are being asked to be waived over at the WTO, analyze the key standpoints being taken, and possible conclusions that can be drawn.

PATENTS AND INDIA: A BRIEF OVERVIEW

Granted to owners of invention, patents are exclusive rights so that the innovation may be used, manufactured, and marketed as long as it meets specific legal requirements. Without the permission of the patent holder, no one else is allowed to produce, use, manufacture, or promote the innovation, spelled out in the legislation. Without the permission of the patent holder, no one else is allowed to produce, use, manufacture, or promote the innovation. The protection provided by a patent registration is typically limited in time, typically 20 years. The patented innovation is considered to be in the public sphere after the term of the patent expires (i.e. available for anyone to exploit). A patentable invention should meet the following criteria: a. be unique, b. involve an inventive step, and c. be capable of industrial application. Patent legislation is intended to promote innovation while also protecting corporations. Successfully negotiating patent law may provide a significant edge to firms and startups over competitors who would otherwise try to steal fresh innovations.⁵ The Patent Act of 1790 marked the beginning of the United States' lengthy history of patents. James Madison, known as the "Father of the Constitution," was instrumental in establishing patent rights in the newly constituted nation. Patent law was created with the intention of "promoting the advancement of science and useful arts," but it has developed since then. Patented innovations have had a tremendous impact on society over the years. Patents were used to protect the cotton gin, Morse code, and even the hula hoop.

Patent rights were initially introduced in India in 1856, and the Patent Act 1970 ("the Patents Act") was enacted in 1970, abolishing all earlier laws. India is also a party to the Paris

⁴ Brian Schwartz, 'Big Pharma lobbyists launch campaign against Biden over Covid vaccine patent waiver' (CNBC, 1 June 2021) <<https://www.cnbc.com/2021/06/01/big-pharma-launches-campaign-against-biden-over-covid-vaccine-patent-waiver.html>> accessed 31 December 2021

⁵ 'Patent Law: Everything You Need to Know' (UpCounsel) <<https://www.upcounsel.com/patent-law>> accessed 15 January 2022

Convention for the Protection of Industrial Property, which was established in 1883, as well as the Patent Cooperation Treaty, which was established in 1970. The Patents and Designs Act 1911 established a product patent regime for all inventions in India. In 1970, however, the government passed the new Patents Act, which made medicines and agrochemical goods ineligible for patent protection. This exclusion was enacted to reduce India's reliance on imported bulk medications and formulations and to promote the development of a self-sufficient domestic pharmaceutical sector. The lack of protection for patented products in pharmaceuticals and agrochemicals has had a substantial effect on the Indian pharmaceutical sector, leading to the development of sizable competence in reverse engineering of pharmaceuticals that are patentable as products all through the industrialized world but are not patentable in India. The creation of the World Commerce Organization (WTO) has resulted in a massive paradigm change in global trade. "One of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry,"⁶ according to the agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS), which was brokered during the Uruguay round trade talks of the General Agreement on Tariffs and Trade. On April 15, 1994, India signed and ratified the GATT, making compliance with the GATT's standards, including the TRIPS agreement, obligatory. As a result, India must adhere to the TRIPS Agreement's basic criteria for patents and the pharmaceutical sector. Patent availability for both pharmaceutical items and process discoveries must now be included in India's patent statute.⁷

THE TRIPS AGREEMENT: TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT

After coming into existence in 1995, TRIPS has been deemed to be the most comprehensive multilateral agreement there is for intellectual property rights. It encompasses copyright and

⁶ Zafar Mirza, 'WTO/TRIPs, Pharmaceuticals and Health: Impacts and Strategies, The Society for International Development' (1999) 42 (4) SAGE Publications, 92-97 <<https://ideas.repec.org/a/pal/develop/v42y1999i4p92-97.html>> accessed 15 January 2022

⁷ Nilesh Zacharias, & Sandeep Farias, 'Patents and the Indian Pharmaceutical Industry - Intellectual Property - India' (*Mondaq*, 20 November 2019) <<https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry>> accessed 15 January 2022

related rights (i.e., the rights of performers, producers of sound recordings, and broadcasting organizations); trademarks, including service marks; geographical indications, including appellations of origin; industrial designs; patents, including the protection of new varieties of plants; integrated circuit layout-designs; and undisclosed information, such as trade secrets and test data.⁸The TRIPS Agreement mandates that Member countries grant patents to any inventions, whether products or processes, in all disciplines of technology, without discrimination, subject to the usual requirements of novelty, creativity, and industrial application. Patents must also be available and patent rights must be enjoyed without regard to the site of the invention or whether items are imported or produced locally (Article 27.1).⁹ In the case of pharmaceutical patents, governments must grant the patent holder exclusive rights for a set amount of time. This means that if a pharmaceutical corporation produces a disease treatment, it has the sole right to commercialize it and charge whatever price it wants. Compulsory licensing, which permits anybody to create, use, or even sell a patented product without the permission of the patent owner, can be used to get around these constraints. However, there are too many institutional impediments in the way for poor countries to implement this option in practice. This means that, in the case of COVID-19 vaccinations, the vaccine is only available to those who need it the most.¹⁰

THE UNDERDEVELOPED AND DEVELOPING COUNTRIES' STANCE

The New York Times reported shortly after the pandemic began that UNICEF could only obtain 28 million masks for LMICs, and only at exorbitant costs; when it was hoping to purchase 240 million masks. According to one stakeholder, an otherwise logical set of criteria for procuring medical supplies has "devolved into an arm-twisting exercise." According to Oxfam, wealthy countries account for 13% of the world's population and have purchased 51% of the promised doses of leading Covid-19 vaccine candidates as of 2020. While the UK and US

⁸ 'Overview: The TRIPS Agreement' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#patents> accessed 31 December 2021

⁹ *Ibid*

¹⁰ Sarah El Gharib, 'COVID-19 Vaccine Intellectual Property Rights: Everything You Need to Know' (*Global Citizen*, 10 September 2021) <<https://www.globalcitizen.org/en/content/covid-19-vaccine-intellectual-property-rights/>> accessed 31 December 2021

have now completely vaccinated more than 50% of their population, smaller countries like African nations have managed to administer less than one dose per person in their population¹¹, highlighting the huge disparity in the levels of Covid-19 vaccination received by countries, with a heavy dependency on the finances of the country. On the 2nd of October, 2020, a proposal was put forward to the WTO by India and South Africa pertaining to the patent rights of the Covid-19 vaccinations. Since then, they have received paramount support from multiple other Member countries. According to the report, the pandemic's global demand has caused severe shortages in many nations, preventing them from efficiently reacting to the outbreak and resulting in many deaths. They've recommended waiving much of the vaccine's intellectual property rights. This exemption would allow any country to manufacture the vaccine with greater design and production flexibility until the World Health Organization declares COVID-19 herd immunity (WHO). This would apply not only to vaccines, but also to diagnostics, pharmaceuticals, and other technology until the pandemic is completely contained. "An effective response to the COVID-19 pandemic requires rapid access to affordable medical products, such as diagnostic kits, medical masks, other personal protective equipment, and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need," India and South Africa wrote in their proposal. The proponents of the waiver have suggested that the monopoly of Big Pharma on vaccine development is unfair, considering that a majority of COVID-19 vaccines have been funded by taxpayers' money.¹²Section 1 on copyright and related rights, Section 4 on industrial designs, Section 5 on patents, and Section 7 on the protection of hidden knowledge in regard to COVID-19 prevention, containment, or treatment are all covered by the waiver. It would remain for a set period of time, as determined by the WTO's General Counsel, and until universal immunization is in place worldwide and the majority of the world's population is

¹¹ Pushkala Aripaka, 'Factbox: AstraZeneca's deals to produce and supply its COVID-19 vaccine' (*Reuters*, 26 May 2021) <<https://www.reuters.com/business/healthcare-pharmaceuticals/astrazenecas-deals-produce-supply-its-covid-19-vaccine-2021-05-26/>> accessed 03 January 2022

¹² Andrea Shalal, Jeff Mason, & David Lawder, 'U.S. reverses stance, backs giving poorer countries access to COVID vaccine patents' (*Reuters*, 5 May 2021) <<https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/>> accessed 06 January 2022

vaccinated. The waiver would be reviewed by members once a year until the pandemic was declared terminated.¹³

South Africa stated that the current TRIPS system is ineffective, citing the failure to get life-saving drugs during the HIV/AIDS pandemic, which claimed the lives of at least 11 million Africans. They received immense support from 375 civil society organizations which with the help of Medecins Sans Frontières (MSF) drafted a joint letter. MSF noted that the R&D underpinning what corporations currently aspire to commercialize via IP was funded by billions of dollars in public sector resources and charity financing. "The problem of worldwide scarcity of COVID-19 vaccine doses will not be remedied as long as COVAX predominantly competes with high-income nations to acquire supply from the same small number of [IP-holding] manufacturers, rather than increasing the number of suppliers," MSF adds. The number of suppliers should be prioritized in global initiatives." Furthermore, according to MSF, firms are opting out of voluntary schemes like the WHO COVID-19 Technology Access Pool (C-TAP) project for equitable vaccination, treatment, diagnostic, and technology distribution. Shyamal Misra, a senior official in India's Ministry of Commerce, said that India would not only be speaking for itself at the WTO ministerial conference in Geneva, which begins Nov. 30, but also for other developing countries with which it collaborates closely. "We expect that the interests of developing countries are not compromised," Misra told an event late on Thursday to discuss India's strategy. India claims that wealthy countries, led by the European Union, Switzerland, and the United Kingdom, are "preventing impoverished countries' access to vaccines," resulting in deaths.¹⁴ Multiple Member countries' expressly voiced their support towards the proposal for the waiver. Guinea's Foreign Minister, IBRAHIMA KALIL KABA, addressed on behalf of the "Group of 77" and China, highlighting the importance of treating COVID-19 vaccinations as a global public good. To combat the epidemic and regain momentum toward the Sustainable Development Goals, he said, fair,

¹³ Waiver from Certain Provision of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (n 2)

¹⁴ Faizan Javed, "India to Push For Patent Waiver For COVID-19 Vaccines At WTO" (*Moneycontrol*, 26 November 2021) <<https://www.moneycontrol.com/news/india/india-to-push-for-patent-waiver-for-covid-19-vaccines-at-wto-7765451.html>> accessed 06 January 2022

timely, and ubiquitous access is required. He urged all countries to combat disinformation and vaccine reluctance by increasing technology and information exchange. He expressed support for scaling up vaccine manufacturing under the trade-related intellectual property rights agreement, citing the worldwide vaccine deficit as a threat to community health and well-being.

On behalf of the Group of Landlocked Developing Countries, ALEXEY TSOY, Kazakhstan's Minister of Health, noted that inequitable access to vaccines is widening the gap between affluent and poor countries. He urged interested parties to avoid making direct, unilateral deals with manufacturers and to provide vaccines to countries in need. According to professional opinion, at least 70% of the world's population must be vaccinated in order to limit the current epidemic, he stated, encouraging COVAX facilitators to enhance planned procurement. He also urged WTO members to take advantage of the trade-related intellectual property rights accord to temporarily boost timely and cheap access to important medical items.¹⁵ A wave of relief and assurance came in for these countries, when the US government voiced its support in May 2021. In statements to reporters, President Biden expressed support for a waiver, reversing the prior US position, and was quickly followed by a statement from Katherine Tai, his chief trade negotiator, who favored WTO deliberations. "This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures," Tai said in a statement, amid growing concerns that large outbreaks in India could allow vaccine-resistant strains of the deadly virus to emerge, jeopardizing the global recovery. His decision comes amid a disastrous outbreak in India, which accounted for 46% of new COVID-19 cases globally in recent times, as well as concerns that the pandemic is spreading to Nepal, Sri Lanka, and other countries. Tedros Adhanom Ghebreyesus, the head of the World Health Organization, termed Biden's decision a "MONUMENTAL MOMENT IN

¹⁵ 'Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting' (*United Nation*, 16 April 2021)
<<https://www.un.org/press/en/2021/ecosoc7039.doc.htm>> accessed 07 January 2022

THE FIGHT AGAINST #COVID19" on Twitter, saying it represented "the wisdom and moral leadership of the United States."¹⁶

Socialist groups have also taken a strong stance supporting the waiver of the IP rights for the vaccination. They have claimed that the true "vaccine bonus" is the profit made at the cost of human lives by these private firms. Pfizer and Moderna are doing what all businesses in a capitalist market must do: hoarding intellectual property so they can produce and sell the vaccines alone. It is up to the global working class and impoverished to put pressure on governments to break the monopoly. This is the only way to achieve the much-needed global vaccine equity. IP laws for Covid vaccines must be lifted immediately so that factories and governments all around the world can begin creating their own vaccines and put a stop to the epidemic once and for all. Furthermore, these multinational pharmaceutical corporations must be placed under democratic public ownership so that all advances in medical science can be shared globally to save and benefit lives.

Pfizer and Moderna would be far more likely to share their work so that they could live in a safe, healthy community if they were publicly owned and democratically run by their workers – the people who actually created the vaccine – rather than wealthy shareholders who are only concerned with their bottom line.¹⁷ In conclusion, several strong standpoints have been taken in support of the proposal put forward by India and South Africa to the WTO for the waiver of the vaccines, citing an urgency to contain the pandemic at the earliest stage possible as well as to ensure that there is no more loss of lives and equity in vaccine dosage amongst all nations, underdeveloped or developed. They have urged the developed nations to reconsider their stance based on the history of the HIV/AIDS pandemic which claimed millions of lives and the flexibility in production it would allow the countries in need to produce these vaccines at an accelerated rate. They have successfully garnered support from multiple groups and will continue furthering their arguments in the next WTO meetings and try to come to an agreement that would benefit all parties involved and save millions of lives.

¹⁶ Andrea Shalal, Jeff Mason, & David Lawder (n 12)

¹⁷ Cathal Curran, 'Big Pharma Makes Billions from Vaccine Apartheid' (*International Socialist Alternative*, 21 December 2021) <<https://internationalsocialist.net/en/2021/12/coronavirus>> accessed 06 January 2022

THE RICH, DEVELOPED COUNTRIES & THE PHARMACEUTICALS' STANCE

In the 21st April session for a special meeting on a "Vaccine for All", the European Union's representative pointed out that the bloc has spent more than €1 billion to support research on anti-COVID vaccines and therapeutics, and has contributed €2.5 billion to the ACT-COVAX Accelerator's Facility, which has exported more than 80 million doses to 42 countries. In addition, in collaboration with the Africa Centres for Disease Control and Prevention, "Team Europe" has mobilized a global recovery package worth over €40 billion and will contribute an additional €100 million in humanitarian support to vaccine efforts. He went on to say that vaccination is a "race against the virus, not a race between countries."¹⁸ Many of the same countries have pledged philanthropic offerings, either in the form of money or extra vaccine doses from what they've already pre-ordered. The European Commission, Canada, Australia, Switzerland, Japan, and a number of other governments use their contributions to COVAX, a global vaccine procurement facility, to deflect attention away from their discriminatory WTO stance. The EU has pledged to treble its contributions to COVAX, bringing the total to €1 billion.¹⁹

The major argument for establishing and safeguarding intellectual property rights is that they act as incentives for innovation, which is the principal source of long-term economic growth and improvements in human life quality. IP rights encourage innovation because they "allow innovators to capture enough of the advantages of their own original activities to justify taking significant risks."²⁰ The information gained from IP-enabled innovations is passed on to inspire new ideas. The preservation of intellectual property rights encourages the spread of innovative technology and fresh know-how both domestically and internationally. Land, labor, and capital have historically been the primary components of production. Perhaps an even more

¹⁸ Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting (n 15)

¹⁹ Aruna Kashyap & Margaret Wurth, 'Rich countries must stop 'vaccine apartheid' | View' (*Euronews*, 11 March 2021) <<https://www.euronews.com/2021/03/11/rich-countries-must-stop-vaccine-apartheid-view>> accessed 07 January 2022

²⁰ Stephen Ezell & Nigel Cory, 'The Way Forward for Intellectual Property Internationally' (*Information Technology and Innovation Foundation*, 25 April 2019) <<https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally>> accessed 07 January 2022

important component in the new pandemic world is the generation of information, which adds substantially to "national wealth." In the twenty-first century, digital and other economic growth is increasingly focused on ideas and knowledge. There would be less fresh information and consequently less innovation if IP rights were not used as incentives. In the short term, undermining private IP rights may accelerate the distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.²¹

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a political lobbying organization that represents more than 30 pharmaceutical companies, including Covid vaccine producers Pfizer and Johnson & Johnson. After President Biden’s pledge to support the waiver proposal, PhRMA allegedly launched an online campaign on Facebook and Google debating his decision.²² After news pieces on this particular move were brought to the public, PhRMA released a public statement: “In the midst of a deadly pandemic, the Biden Administration has taken an unprecedented step that will undermine our global response to the pandemic and compromise safety. This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines. This change in longstanding American policy will not save lives. It also flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery. This decision does nothing to address the real challenges to getting more shots in arms, including last-mile distribution and limited availability of raw materials.

²¹ ‘Transforming Our World: The 2030 Agenda for Sustainable Development’ (*United Nation: General Assembly*, 21 October 2015)

<https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_70_1_E.pdf> accessed 07 January 2022

²² Brian Schwartz (n 4)

These are the real challenges we face that this empty promise ignores. In the past few days alone, we've seen more American vaccine exports, increased production targets from manufacturers, new commitments to COVAX, and unprecedented aid for India during its devastating COVID-19 surge. Biopharmaceutical manufacturers are fully committed to providing global access to COVID-19 vaccines, and they are collaborating at a previously unimaginable scale, including more than 200 manufacturing and other partnerships to date. The biopharmaceutical industry shares the goal to get as many people vaccinated as quickly as possible, and we hope we can all re-focus on that shared objective."²³

Multiple public platforms and research papers have furthered the above points of view and provided further arguments to support the same. Without the promise of IP protection, scientists would be unable to devote the necessary human and financial resources to such R&D, as there would be no motivation to invest the time and effort to a promising but difficult invention. Similarly, venture funders would refuse to invest billions of dollars in research if any firm could simply take the successful result and create a treatment without paying for R&D costs; in this case, recouping the initial investment would be nearly hard. As a result, without the promise of intellectual property protection, the technology that underpins the most advanced and promising COVID-19 vaccines would very certainly never have been produced. While referring to South Africa's mention of the HIV/AIDS event, it was pointed out that in 2003, the World Trade Organization (WTO) permitted for the importation of pharmaceuticals under a compulsory license, but many developing nations failed to put in place any system that would allow them to take advantage of the flexibility.²⁴

Two additional factors render the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at reasonable rates, and several announced plans for extensive not-for-profit sales. Second, the proposed waiver will do nothing to

²³ 'PhRMA Statement on WTO TRIPS Intellectual Property Waiver' (*PhRMA*, 5 May 2021) <<https://phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver>> accessed 07 January 2022

²⁴ Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* (*South Centre and World Health Organization*, 2006) <<https://apps.who.int/iris/handle/10665/43503>> accessed 07 January 2022

address the issue of a lack of capacity and the necessity of transferring technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries; in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.²⁵ Another strong assertion made is that pharmaceutical corporations have been actively signing voluntary licensing arrangements with various generic drug producers to scale up the production of COVID-19 medication, contrary to the TRIPS Council supporters' assurances. In May 2020, the US Food and Medication Administration (FDA) and the European Medicines Agency approved Gilead's antiviral drug Remdesivir for emergency use in COVID-19 treatment. To satisfy the increased demand for the medicine following the authorization for use against COVID-19, Gilead provided non-exclusive voluntary licenses to generic companies in India, Egypt, and Pakistan. They have also communicated that the international system was created to deal with any situation, including global pandemics like COVID-19, by providing both incentives for industry to invest large amounts of time and money in research and development, as well as tools for developing countries to use in their fight against COVID-19. Despite claims from leading NGOs that TRIPS adjustments such as the aforementioned compulsory license regime are too complex to use or that risks from developed countries limit their use, a study by leading public health advocates found that the flexibilities have "been used more frequently than commonly assumed and proven effective for procuring generic versions of essential medicines." With regards to safety, it was put forward that in order to reduce the danger of counterfeit and inferior medications, effective and proactive IP acquisition is necessary. IP enforcement methods play a critical role in preventing the spread of counterfeit and illegal medications on the market. During these important times, IP enforcement can play a greater role in protecting the public. Waiving all COVID-19-related IPRs increases the possibility of unsafe or counterfeit vaccines circulating in supply chains and being marketed to unwary governments, endangering millions of people and eroding public faith in vaccines. To draw to a close their

²⁵ Reed F. Beall, Rosanne Blanchet & Amir Attaran, 'In which developing countries are patents on essential medicines being filed?' (2017) 13 (38) *Globalization and Health*

arguments, there is scant indication that IPRs are hindering the development and dissemination of COVID-19 vaccines and therapies. It appears unnecessary and perhaps damaging to waive all IPRs linked with COVID-19 before such proof is produced. Rather, efforts should be undertaken to strengthen supply chains, modernize infrastructure, and guarantee that distribution can give the amount of access required to prevent a worldwide pandemic.

THE CURRENT STATUS OF THE IPR WAIVER

India and South Africa submitted a revised proposal to the WTO in May 2021, however, no substantive decision was made. According to an official, India has requested an emergency meeting of the World Trade Organization's (WTO) General Council this month in Geneva to discuss the world trade body's proposed response package, which includes a patent waiver proposal, to deal with the pandemic amid rising coronavirus infections globally. India has requested that the TRIPs (Trade-Related Aspects of Intellectual Property Rights) waiver proposal for dealing with the epidemic be included in the WTO's planned response package, expressing regret over the lack of movement on the issue.

POSSIBLE SOLUTION

With the debate over the waiver reaching no acceptable to all parties' conclusion, theories regarding an agreeable situation for all stakeholders have emerged. One possible way out would be to provide heavy compensation to the pharma companies involved in the manufacturing process of the Covid-19 vaccination while also ensuring that if the IP rights have wavered, they are done so responsibly and distributed amongst trustworthy manufacturers in the underdeveloped and developing countries by their respective and accountable government bodies. Another key factor to look into would be continuing efforts to increase the supply of all medical equipment to the underdeveloped and developing nations to allow the world to move ahead of the pandemic and develop a herd immunity ensuring that the waiver doesn't last indefinitely putting some ease to the developed nations' concerns.

CONCLUSION

Vaccine production is a complex process including a variety of raw materials and components across the value chain. Vaccine manufacture presents a number of problems, ranging from locating active pharmaceutical components and machinery through testing, packaging, and storage. The global pandemic will not be solved by waiving or easing intellectual property rights over anti-COVID technology. However, it has the potential to remove a number of impediments. It might also be argued that issuing a waiver would be a sensible option, considering that vaccine research and development has received more than \$12 billion in government support. Increasing worldwide vaccination availability will be a big assist to attempts to limit COVID-19, notwithstanding Big Pharma's stance on waiver refusal. Efforts to simplify IP rules, on the other hand, may tip the scales in favor of COVID-19 containment. Increasing the worldwide availability of vaccinations would be a huge help in the fight against COVID-19. Parallel to initiatives to relax IP regulations, the balance of power may shift toward containment.