

Are Pharmaceutical Companies Ready to Distribute Vaccines and Medical Supplies in the Event of a New Pandemic? An Investigation into the Intricacies Between Intellectual Property Rights v. Human Rights

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Abstract

This paper will delve into the critical intersection of business interests and human rights, particularly focusing on the role of pharmaceutical companies in ensuring equitable access to essential medical supplies and vaccines during pandemic and other public health emergencies whilst also retaining these companies Intellectual Property Rights. The paper will look into the UN Guiding Principles on Business and Human Rights, emphasizing on the obligation of business enterprises such as pharmaceutical companies to facilitate in accessible and affordable medical supplies, especially for low-income countries. This paper will analyze how pharmaceutical companies have fulfilled their human rights obligations during the public health emergency of international concern like the COVID-19 while also upholding their intellectual property rights, highlighting both the shortcomings and successes. Also considering lessons learned from the recent pandemic, the paper will also propose strategies to strike a balance between business interests and human rights. This article aims at contributing to the ongoing discourse surrounding business and human rights by offering recommendations that can guide the actions of business enterprises in promoting equitable access to essential medical supplies in times of public health crisis in future.

Keywords: Human Rights, Intellectual Property, COVID-19, Pandemic, right to health, equitable access, medicines, vaccines.

I. Introduction

It is evident from the recent COVID-19 pandemic that vaccines have been consistently proven to be one of the most effective tools for fighting pandemics. However, during the peak of the COVID-19 pandemic, the distribution of available vaccines to all parts of the world saw a great number of inequalities¹. As of March 2023, almost 5.55 billion people around the world were inoculated with

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¹ Akbar F.Habibilla, 'Vaccine Politics: Comparison of Acceptance of COVID-19 Vaccines Produced by Democratic and Non-Democratic Countries', *Jurnal Politik* p.130, volume 9:1, 2023, p. 131-132, available at <https://scholarhub.ui.ac.id/cgi/viewcontent.cgi?article=1157&context=politik>.

vaccines², but most of the vaccines had gone to the wealthy nations while most part of the developing and underdeveloped world were struggling to procure and inoculate their population. This disparity in access to vaccines not only prolonged the pandemic in many regions but also put a lot of question about the current global health governance system³.

As the world was grappling with COVID-19 and the inequalities in the distribution of vaccines, countries like India and South Africa submitted a proposal for a temporary waiver of provisions under the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS agreements) in October 2020⁴. The waiver was brought forward to temporarily suspend the implementation, application and enforcement of provisions related to copyrights, industrial design, patents, undisclosed information etc.⁵ and that these IP protections do not create barriers to timely accessibility to vaccines and other medical supplies⁶. The proposal also suggested that the waiver should continue until vaccination has been widespread and majority of the world population has developed for an immunity⁷.

This proposal would have allowed the World Trade Organization (hereinafter WTO) members to let go of certain application, implementation, and enforcement of intellectual property rights protections for production of medical products. However, it came with a lot of resistance from vaccine manufacturing nations and the big pharmaceutical companies themselves most of them citing intellectual property rights concerns.

This debate reignited the everlasting discussions on human rights considerations during the application of the WTO and TRIPS Agreements framework, particularly in the context of the public health emergencies of international concern and the scarcity of vaccines in the least developed parts of the world. Finding a balance between intellectual property rights and the equitable distribution of life-saving resources remains a complex challenge under international law and needs certain considerations⁸. The relationship between intellectual property rights and human rights to health has always been a complex one, and the global community have always been divided on the issues surrounding it and scholars overlooked the issue for years⁹.

This article investigates the preparedness of pharmaceutical companies to distribute vaccines and medical supplies equitably in the event of a new pandemic in light of the complexities in the application of intellectual property rights and the human right to health during public health emergencies. The article adopts a qualitative doctrinal research approach where ideas were drawn

² Josh Holder, 'Tracking Coronavirus Vaccinations Around the World', *The New York Times*, New York City, 13 March 2023, available at <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>, accessed on 22nd May 2023.

³ Habibilla (n 1), pp. 131-132.

⁴ Aditi Mukherjee Chakravorty, Shweta Rathore & Himanshu Shukla, 'Compulsory Licence vs. TRIPS Waiver: Analysing Legal - Political Dimensions', *International Journal of Food and Nutritional Sciences* p.1455, volume 11:10, 2022, p.1459, available at <https://www.ijfans.org/uploads/paper/9349f370907ec1939f4d2e6e1b788b8f.pdf>.

⁵ *Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19 (hereinafter Waiver)*, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India and South Africa, IP/C/W/669, 2020, para. 12.

⁶ Ibid, para. 3.

⁷ Ibid, para. 13.

⁸ Peter K. Yu, 'Intellectual Property and Human Rights 2.0', *University of Richmond Law Review* p. 1375, volume 53:4, 2019, p. 1429.

⁹ Ibid, pp. 1394-1395.

from existing scholarly publications, online secondary sources, legal texts, international human rights instruments etc. They were selected and critically studied based on their relevance to the topic to ensure balanced analysis and while it does not introduce new concept but rather re-examines the ideas in the context of this article.

II. Right to health and intellectual property rights as human rights

The International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR) adopted in 1966 and enforced in 1976, is a core human right treaty concerning the “economic, social and cultural” rights¹⁰. It has a total of 173 state parties¹¹. The treaty safeguards both the right to health and intellectual property rights as fundamental human rights. According to Article 12 of ICESCR, the state must recognize the right of every individual to the enjoyment of the highest attainable standard of physical and mental health¹². The right to health is a legally binding commitment enshrined under human rights instruments such as the constitution of World Health Organization (WHO). The preamble of the WHO mentions that, “the enjoyment of the highest attainable standard of health as one of the fundamental rights of every individual”¹³. Every state is obligated to provide healthcare services to its citizens and is a universally protected right under various International Human Rights Laws, and every individual is legally entitled to such protections¹⁴.

Other human rights treaties, such as the UN Convention on Elimination of All Forms of Discrimination Against Women 1979, (CEDAW), under Article 14(b) mentions that women should have the right, “to have access to adequate health care facilities”¹⁵. Similarly, article 28 of the UN Convention on The Rights of Persons with Disabilities, 2006, (CRPD) mentions that, “state parties recognize that persons with disabilities have the right to the enjoyment of highest attainable standard of health...”¹⁶. Additionally, the UN Convention on The Rights of Child, 1989, (UNCRC) under article 27 mentions that state parties should “recognize the right of every child to a standard of living adequate for the child’s physical, mental development”¹⁷. Similarly, the Constitutions of various countries recognize the right to health and accessibility and affordability of medicines as a crucial element of the realization of an adequate standard of living. The constitution of the United States of America also recognizes the right to health as an integral part of the right to life as a result of which the judiciary has been able to lay down principles recognizing and interconnecting the relationship between the right to health as right to life¹⁸.

¹⁰ Depository, ‘Status of Ratification: Human Rights’, *United Nations Treaty Series (hereinafter UNTS)*, Chapter IV, No.3, p.1, available at <https://treaties.un.org/doc/Publication/MTDSG/Volume%20I/Chapter%20IV/IV-3.en.pdf>.

¹¹ Ibid

¹² *International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR)*, 3 January 1976, 993 UNTS 3, 16 December 1966, art. 12.

¹³ *Constitution of World Health Organization*, 17 November 1947, UNGA/RES/13, 22 July 1946, Preamble.

¹⁴ O. Lawrence, J.D Gostin & Devi Sridhar, ‘Global health and the law’, *New England Journal of Medicine*, Massachusetts, vol 370:18, 1 May 2014, pp. 1736-1738, available at <https://www.nejm.org/doi/full/10.1056/NEJMr1314094>, accessed on 10 July 2023.

¹⁵ *Convention on the Elimination of All Forms of Discrimination Against Women*, Art. 14, 18 December 1979, 1249 UNTS 13, [hereinafter CEDAW].

¹⁶ *Convention on the Rights of Persons with Disabilities (hereinafter CRPD)*, 3 May 2008, UNGA Res.A/Res/61/106, 24 January 2007, art.25.

¹⁷ *Convention on the Rights of the Child (hereinafter CRC)*, 2 September 1990, 1577 UNTS 3, 20 November 1989, art. 27.

¹⁸ A.K.A Kolawole, ‘The right to life and the right to health. Any nexus?’, *OIDA Journal of Sustainable Development*, vol 2:5, 22 February 2011, p.100., available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1767507.

Similarly, ICESCR under 15 affirms that every state party to the treaty recognizes every individual's right to benefit from scientific progress and its applications. Additionally, the author of such scientific innovation shall enjoy the protection of both material and moral interests which comes from their literary, or artistic production.¹⁹ Article 15(1)(b) of the ICESCR recognizes the right to “share in scientific advancements and its benefits,” while Article 15(1)(c) grants the right to the “protection of the moral and material interests” arising out of scientific, literary or artistic works respectively. In essence, these provisions are closely linked to the human right to health as outlined under Article 12 when read alongside Article 15(1)(b) and Article 15(1)(c)²⁰.

III. TRIPS waiver proposal

In October 2020, middle-income countries like India and South-Africa put forth a proposal requesting the waiving of the implementation, application and enforcement of certain provisions related to patents, industrial designs, undisclosed information among others under the TRIPS Agreement²¹. The proposal offered WTO members a choice to temporarily waive the application, implementation and enforcement of protection for various forms of intellectual property rights related to vaccines, essential medicines and other technologies used to fight against the pandemic. The proposal was not only limited to the waiver of patent rights under the TRIPS Agreement but also included issues related to the manufacturing of the vaccines and diagnostics, and the failure of states to supply such essentials in sufficient quantity and at affordable prices, and meet the global demands at the same time. India and South Africa, who were also joined by other supporters in a revised proposal who primarily raised concerns around intellectual property and other legal complexities associated with it in the light of public health emergency of international concern like COVID-19²².

A new proposal with further refinements, with primary focus on the prevention, treatment, and control of COVID-19, was again submitted on 25 May 2021, which expanded the scope to incorporate products and technologies, including their ingredients and composition, and the manufacturing methods and processes²³. The new proposal was based on the provisions outlined under Article IX (3), (4), and (5)²⁴ of the Marrakesh Agreement Establishing the World Trade Organization (WTO). The revised communication was put forward by the African Group, Bolivia, Egypt, Eswatini, Fiji, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan,

Vanuatu, Venezuela and Zimbabwe including India and South-Africa.²⁵

¹⁹ ICESCR (n 12), art.15.

²⁰ Nishant Sirohi, ‘Right to equitable access to COVID-19 Vaccination-if not now, then when?’, *Observer Research Foundation*, 2021, available at https://www.orfonline.org/expert-speak/right-equitable-access-covid19-vaccination-if-not-now-then-when/?fbclid=IwAR10x7ImQSV7s_iIhLjyumbuzLYLk1Phmy9kkLyTU-0fr1RoxztkSGB-nuo, accessed on 11 March 2022.

²¹ Waiver (n 5), para 13.

²² Chakravorty (n 4), p. 1455.

²³ Chakravorty (n 4), p. 1459.

²⁴ *Uruguay Round Agreement: Marrakesh Agreement Establishing the World Trade Organization*, 1 June 1995, 1867 UNTS, Marrakesh, 14 April 1991, art. IX.3, 3 and 5.

²⁵ *Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19: revised decision text*, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the African group et.al. IP/C/W/669/Rev.1, 21 May 2021, para. 1, available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274473,274404,274395,274268,274269,274271,274186,273996,273770,273787&CurrentCatalogueIdIndex=6&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True

Low and middle-income countries have time and again raised concerns about the substantial barriers posed by IP but have been met with disregard from the high-income countries and overlooked the historical experiences and lessons particularly from the efforts to overcome IP limitations for HIV/AIDS treatment²⁶. Even though safe and effective vaccines are necessary for fighting against COVID-19, patents and IP rights related to technologies create legal obstacles to equitable access and fair distribution²⁷.

Position of advocates of TRIPS waiver

The principal argument of the proponents of the TRIPS waiver was that in the light of the pandemic every nation should have the right to manufacture its own vaccines. Most of the NGOs working for health and certain governments argued that suspending certain IPRs will allow manufacturers globally to produce vaccines and get speedier access²⁸. The proposal waiver initially pushed by India and South Africa rapidly gained momentum and received support from various stakeholders, including nations, international human rights and humanitarian organizations. Director General of WHO, Dr Tedros Ghebreyesus also affirmed that in order to fight the pandemic, “waiving intellectual property rights as South Africa and India have suggested” as one of the options²⁹. Similarly, both Human Rights Watch and Amnesty International have stressed that governments shouldn’t block the temporary waiver of some intellectual property rules which might help in boosting global access to COVID-19 vaccines³⁰. The TRIPS waiver proposal was welcomed warmly by the civil society. On 16th February 2022, the Global Civil Society Organizations, which included a group of over 200 CSOs from all over the world, wrote an open letter to the Director General of WTO in support of the waiver proposal and urging for a bold and meaningful outcome of the waiver proposal and ensure timely and affordable access to medical supplies³¹. The goal of the waiver proposal was to reduce difficulties for countries that are capable of producing their own vaccines, such as India and South Africa. However, the proposal was heavily opposed by the big and established pharmaceutical industries and instead of waiver, they were urging the world community to share their vaccines with low-income through COVAX mechanism³².

²⁶ Aruna Kashyap, ‘Whoever finds the vaccines must share it’, *Human Rights Watch*, 29 October 2020, available at <https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency>, accessed on 25 June 2022.

²⁷ Mario Gaviria & Buruc Kilic, ‘mRNA-1273 Vaccine Patent Landscape (For NIH-Moderna Vaccine)’, *Public Citizen*, 16 November 2020, available at <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/>, accessed on 29 June 2022.

²⁸ Philip Stevens, ‘To produce vaccines, intellectual property rights may be waived. That’s counterproductive’, *Hinrich Foundation*, 7 June 2022, available at <https://www.hinrichfoundation.com/research/article/tech/vaccines-intellectual-property-ip-rights-waived/>, accessed on 18 August 2023.

²⁹ Tedros Adhanom Ghebreyesus, ‘Waive Covid vaccine patents to put world on war footing’, *WHO*, 7 March 2021, available at <https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing>, accessed on 17 June 2023.

³⁰ News, ‘Urgently Waiver Intellectual Property Rules for Vaccine, Right to Life, Public Health Demand Extraordinary Cooperation, Sharing’, *Human Rights Watch*, Geneva, 10 December 2020, available at <https://www.hrw.org/news/2020/12/10/urgently-waive-intellectual-property-rules-vaccine>, accessed on 22 June 2023; Press Release, ‘Urgently Waiver Intellectual Property Rules for Vaccine, Right to Life, Public Health Demand Extraordinary Cooperation’, *Amnesty International*, 10 December 2020, available at <https://www.amnesty.org/en/latest/press-release/2020/12/urgently-waive-intellectual-property-rules-for-covid-19-vaccine/>, accessed on 28 June 2023.

³¹ Open Letter, ‘Civil Society Open Letter to the WTO Director General’, *Global Civil Society Organizations*, 22 February 2022, available at <https://msfaccess.org/civil-society-open-letter-wto-director-general>, accessed on 11 July 2024.

³² COVAX was a global collaboration of the vaccines pillar of Access to COVID-19 Tools (ACT) in order to accelerate the development, production and access to COVID-19 vaccines for every country in the world, COVAX, ‘Working for Global Equitable Access to COVID-19 Vaccines’ *WHO*, 2020, available at <https://www.who.int/initiatives/act-accelerator/covax>.

Proponents of the human right to health argument

The advocates of the patent waiver argued on the premise that the right to access essential medicines and vaccines is crucial for the human right to health, and that should take precedence over IP protections. They further asserted that the provisions under the TRIPS agreements should not be interpreted in a way that hinders any human being's right to affordability and accessibility of essential medicines and vaccines.

In addition to that, Article 7 of the TRIPS Agreement³³ provides about the protection and enforcement of intellectual property rights that contribute to the promotion of technological innovation in a manner conducive to social and economic welfare and to a balance of rights and obligations.

In March 2020, the Office of the UN High Commissioner for Human Rights (OHCHR) urged all governments to introduce measures to limit the spread of the coronavirus and undertake actions to reduce the negative impact on the lives of the people³⁴. Various writers suggested that the statement issued by the UN High Commissioner is justified because public taxes significantly fund medical and vaccine research. There is a tendency for IP protections to favor business interests over public health during any public health emergencies. Another key argument raised by the advocates of the TRIPS waiver was that while IP protections as part of human rights give competitive advantage to the author, in the case of public health emergencies of international concern, during public health emergencies, the focus should be on protection of public health rather than protecting business and economic concerns³⁵.

Support from vaccine manufacturing countries

In an unexpected move from some of the vaccine manufacturing countries like China, Russia, and even the United States of America (USA) came forward in support of the waiver proposal. In April 2020, the Trump administration changed its stance in regards to TRIPS waiver, and following that, an announcement was made on 5 May 2021 by the following US President Joe Biden calling the current situation of pandemic as an extraordinary circumstance and it called for extraordinary measures³⁶ which was affirmed by United States Trade Representative Katherine Tai, who also released a statement³⁷. As one of the largest vaccine manufacturers in the world, the support from the US was crucial. This was followed by other countries like Brazil and Canada, which also expressed their support for the patent waiver. Brazil's Senate also approved a bill to suspend patent protection for COVID-19 vaccines, tests, and medication during the course of the pandemic³⁸ which was a positive

³³ *Agreement on Trade-Related Aspects of Intellectual Property Rights (herein after TRIPS)*, 1 January 1995, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C UNTS 229, Marrakesh, 15 April 1994, art.7.

³⁴ Press release, 'Coronavirus: Human rights need to be front and centre in response, says Bachelet', OHCHR, 6 March 2020, available at <https://www.ohchr.org/en/press-releases/2020/03/coronavirus-human-rights-need-be-front-and-centre-response-says-bachelet>.

³⁵ Nabeel Mahdi Althabhwawi & Ali Adil Kashef Al-Ghetaa, 'The COVID-19 vaccine patent: a right without rationale', *Med Humanit*, vol 49:1, 6 May 2022, p. 1-2.

³⁶ Julian Borger, 'US declares support for patent waiver on Covid-19 vaccines', *The Guardian*, Washington, 5 May 2021, available at <https://www.theguardian.com/world/2021/may/05/us-declares-support-for-patent-waiver-on-covid-19-vaccines>, accessed on 27 November 2022.

³⁷ Statement, 'Statement from Ambassador Kai on the COVID-19 Trips waiver', *Office of United States Trade Representative*, 05 May 2021, available at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

³⁸ Ricardo Brito, 'Brazil senate votes to suspend patent protection on COVID-19 vaccines', *Reuters*, Brasilia, 30 April 2021, available at <https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30/>, accessed on 28 June 2023.

step from the Brazilian government.

Similarly, China also came forward in support of a temporary patent waiver when in May 2020, they declared that they are committed to making COVID-19 vaccines more accessible and affordable to middle- and lower-income countries and make it a public good. As per the news published in May 2022, China has distributed around 2.2 billion doses of Chinese vaccines to over 120 countries and international organizations around the world³⁹. Similarly, China actively pursued vaccine diplomacy throughout the pandemic and mentioned that they supported the TRIPS waiver proposal⁴⁰. Similarly, Russian President Vladimir Putin also supported the idea of a waiver on patent protection for COVID-19⁴¹. China, as a key vaccine producer and supplier, announced that they are ready to relax IP protection and support the TRIPS waiver for COVID-19 vaccines. This wave of support for vaccine manufacturing countries showed a sense of prioritization of human health over business interests during public health emergencies.

Position of big pharmaceutical companies

The vaccine production industry is concentrated amongst a handful of pharmaceutical companies, as in 2015 alone 25 largest pharmaceutical companies accounted for 73% of all pharmaceutical sales⁴². Most pharmaceutical companies have gained a lot of profit since the start of the pandemic. For the first time in the history of any pharmaceutical company, Pfizer reached a milestone of \$100 billion in annual revenue while its BioNTech partnered vaccine, Comirnaty was at \$37.8 billion in revenues⁴³. All medicines and vaccines approved by the Food and Drug Administration (FDA) in the United States come from few pharmaceutical companies. The capacities of pharmaceutical companies were put to a test during the COVID-19 pandemic where they were able to develop vaccines in a limited amount of time. The responsibility to develop drugs, production, and distribution of essential medical supplies during the pandemic was swiftly given to pharmaceutical companies, giving them greater authority over the accessibility and affordability of medical supplies with limited government intervention⁴⁴ thus, shifting the power dynamics from the state government to these companies.

High-income countries have heavy investments in pharmaceutical industries. Pharmaceutical companies are the biggest contributors to the global economy, and the sector's research and development efforts itself generate significant economic impact⁴⁵. High-income countries mostly favor these pharmaceutical companies with policies inclined towards benefiting them.

³⁹ Huaxia, 'China has provided over 2.2 billion COVID vaccine doses to the world', *Xinhuanet*, 11 May 2022, available at <https://english.news.cn/20220511/820550385ede4bd7950adf3679a759e5/c.html>, accessed on 5 July 2023.

⁴⁰ Business Today, 'China supports TRIPS waiver on COVID-19 vaccines proposed by India, South Africa', *Business Today*, 18 May 2021, available at <https://www.businesstoday.in/latest/economy-politics/story/china-supports-trips-waiver-on-covid-19-vaccines-proposed-by-india-south-africa-296427-2021-05-18>, accessed on 5 July 2023.

⁴¹ AFP, 'Putin Backs Russia Waiving Patents on Its Covid Jabs', *The Moscow Times*, Moscow, 6 May 2021, available at <https://www.themoscowtimes.com/2021/05/06/putin-backs-russia-waiving-patents-on-its-covid-jabs-a73830>, accessed on 5 July 2023.

⁴² Fred D Ledley et.al., 'Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies', *JAMA*, 3 March 2023, available at <https://pubmed.ncbi.nlm.nih.gov/32125401/>, accessed on 12 June 2023.

⁴³ Kevin Dunleavy, 'The Top 20 pharma companies by 2022', *FIERCE Pharma*, 18 April 2023, available at <https://www.fiercepharma.com/pharma/top-20-pharma-companies-2022-revenue>, accessed on 27 July 2023.

⁴⁴ Owen Dyer, 'COVID-19: Moderna Seeks to Exclude US Government Scientists from Vaccine Patents, Despite Public Investment', *BMJ*, 12 November 2021, available at <https://www.bmj.com/content/375/bmj.n2781>, accessed on 12 April 2023.

⁴⁵ Hannah Burke, 'Why are pharmaceutical companies so important?', *Proclinical*, 27 August 2020, available at <https://www.proclinical.com/blogs/2020-8/why-are-pharmaceutical-companies-important>, accessed on 2 September 2023.

Most pharmaceutical companies are routinely opposed to the idea of TRIPS waiver on the grounds that waiving IP protection could lead to limited scope for scientific innovations. The argument of these companies was based on the idea that IP rights are essential for innovators to earn profits and use those profits to fund high-risk research and development in the pharmaceutical field. Pfizer's chairman and CEO publicly expressed his dissatisfaction over the TRIPS waiver proposal, which could discourage scientific investments, particularly hurting small biotech innovators who rely on investors for their support⁴⁶. The argument presented by the big pharmaceutical companies was premised on the idea that the IP rights are essential for innovators to earn the returns necessary for further research and development. Most big companies contended the idea that IP protections have limited the access to patented COVID-19 vaccines but instead asserted that the focus should be on limiting trade restrictions, distribution bottlenecks, and scarcity of materials to produce vaccine.⁴⁷

Alternative to TRIPS waiver as put forth by the EU

The EU has time and again mentioned that rather than altering IP frameworks, priorities should be shifted towards ensuring equitable global access to vaccines, diagnostics, therapeutics, and keeping supply chains open etc.⁴⁸ Article 31 of TRIPS Agreement mentions the non-consensual use of the patent without any authorization from the author of the patent right holder, which includes issuance of compulsory license⁴⁹. As per the concern raised by most developing countries regarding the potential impact of patents in the pharmaceutical sector, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health in November 2001⁵⁰. The provision related to compulsory licensing has been mentioned under paragraph 5(b) of the Doha Declaration on TRIPS and Public health which states that “each the members has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are to be granted”⁵¹.

Public interest issues are unarguably the strongest grounds for the issuance of compulsory licenses, which include public health emergencies of international concern such as COVID-19. Under Article 31 of the TRIPS Agreement, states have the authority to issue a compulsory license⁵². This allows a third state party of the WTO to use patented goods or products with the patent owner's approval under limited conditions, such as public health emergencies⁵³. Similarly, as per para 6⁵⁴ of the Doha Declaration, TRIPS Agreement and Public Health, instructs the TRIPS Council to provide certain

⁴⁶ Albert Bourla, 'An Open Letter from Pfizer Chairman and CEO to Colleagues', *Pfizer*, 7 May 2021, available at https://www.pfizer.com/people/leadership/executives/dr-albert_bourla, accessed on 22 June 2023.

⁴⁷ Jillian Kohler, Anna Wong & Lauren Taylor, 'Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders', *Health Hum Rights*, December 2022, pp. 159-162, available at <https://pubmed.ncbi.nlm.nih.gov/36579316/>, accessed on 21 March 2023.

⁴⁸ European Parliament, 'Meeting the Global Covid-19 challenge: effects of waiver of the WTO TRIPS agreement on Covid-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries', *Official Journal of the European Union*, 2022/C 67/05, 10 June 2021, para. 1-6, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021IP0283>, accessed on 27 August 2023.

⁴⁹ TRIPS (n 33), art. 31.

⁵⁰ Carlos M. Correa, 'Guide for the Granting of Compulsory licenses and Government Use of Pharmaceutical Patents', *World Health Organization*, Geneva, January 2009, pp. 1-3, available at https://apps.who.int/iris/bitstream/handle/10665/70096/WHO_PHL_2009.1_eng.pdf?sequence=1&isAllowed=y, accessed on 12 July 2023.

⁵¹ *Doha Declaration on the TRIPS agreement and Public Health (hereinafter Doha Declaration)*, WTO Ministerial Conference, 14 November 2001, para 5(b).

⁵² TRIPS (n 33), art. 31.

⁵³ Doha Declaration (n 51), para. 5(b).

⁵⁴ Doha Declaration (n 51), para. 6.

solutions for WTO members with limited manufacturing capacities and cannot make use of such compulsory licenses. But compulsory licensing can still only be allowed under conditions aimed at protecting the legitimate interests of the patent holder⁵⁵. In early months of 2021, Bolivia notified the WTO of its intention to buy COVID-19 vaccines based on Article 31bis mechanism of the TRIPS agreement, which allows the WTO to issue compulsory licenses without the permission of patent holders and export medicines that lack adequate manufacturing capabilities⁵⁶. After a failed attempt by Canada's manufacturing company Biolyse to receive a voluntary license from Johnson & Johnson, it considered seeking for compulsory license under Canada's Access to Medicines Regime (CAMR) to supply around 15 million vaccines to Bolivia. However, the Canadian government made no decision on the request⁵⁷. Canada was still firm in the position that compulsory licensing mechanisms under the TRIPS agreement were enough in place of a complete TRIPS waiver.

IV. Human rights obligation of pharmaceutical companies

While it is generally understood that states are the primary duty-bearers under international human rights law, the recent COVID-19 pandemic and the major role of business enterprises, especially pharmaceutical companies, have compelled the world community to clarify human rights obligations of such business enterprises⁵⁸.

Current understanding under the international law regime

At the moment, there is a limitation of binding international law mechanisms to enforce business enterprises like the pharmaceutical companies and hold them accountable for violating any human rights obligations. Even though ensuring access to medicine is part of the core obligation of governments, private companies cannot be directly held accountable for failing to do so unless national laws allow⁵⁹. However, some international law documents mention the human rights obligations of business enterprises like pharmaceutical companies. Para 42 of General Comment No.14 of ICESCR on the right to health mentions private business sectors' responsibilities in realizing the right to health⁶⁰. Similarly, General Comment No. 24 of ICESCR under para 2 mentions the growing impact of business activities on the enjoyment of specific covenant rights relating to health, among others⁶¹.

The constitution of the WHO and the ICESCR both reaffirm the obligation of governments to ensure the provision of medical services for their citizens. South Africa is one of the pioneer

⁵⁵ Factsheet, 'TRIPS and Pharmaceutical patents', *WTO OMC*, p. 4, available at https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf.

⁵⁶ Publications, 'Article 31bis of the Agreement on Trade-Related Aspects of Intellectual Property Rights', *WTO Analytical Index*, p. 4, available at https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

⁵⁷ MSF Briefing Document, 'Compulsory Licenses, The Trips Waiver and Access to Covid-19 Medical Technologies', *Médecins Sans Frontières (MSF)*, May 2021, available at https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

⁵⁸ Sirohi (n 20).

⁵⁹ Rosalind Turki, 'Upholding Human Rights in the Wake of COVID-19: Time to Strengthen Pharmaceutical Accountability', *Health and Human Rights Journal*, vol 24:2, December 2023, pp. 206-209, available at <https://www.hhrjournal.org/wp-content/uploads/sites/2469/2022/12/turkie.pdf>, accessed on 25 July 2023.

⁶⁰ *General Comment No. 14 on The Right to the Highest Attainable Standard of Health (Art. 12)*, 11 August 2000, UN Committee on Economic, Social and Cultural Rights (CESCR), E/C.12/2000/4, para.42.

⁶¹ *General Comment No. 24 on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities*, 10 August 2017, UN Committee on Economic, Social and Cultural Rights (CESCR), E/C.12/GC/24, para. 2.

countries to make legal provisions within the country to tailor its laws towards affordable medicines for its citizens under its 1997 Medicines Act. In 1998, a group of 39 multinational companies sued the South African government, claiming that their actions violated the TRIPS agreement, which was later withdrawn due to it being a weak case and widespread condemnation from the international community⁶². However, this case did highlight the need to highlight TRIPS flexibilities in light of public health.

During the peak of the COVID-19 pandemic, the Committee on ICESCR released a statement on universal and equitable access to vaccines reaffirming that state parties have a duty to prevent IP and patent laws from undermining the enjoyment of economic, social and cultural rights and cannot make vital public goods like vaccines and medicines inaccessible to developing parts of the world as a result of unreasonable costs⁶³. The committee also goes further to mention that “intellectual property is not a human right but a social product with a social function⁶⁴. The Committee on ECSR also reiterated the duty of states to cooperate in the context of COVID-19, which extends to sharing of the research, medical equipment and supplies, and best practices in combating the COVID-19 pandemic⁶⁵. The ‘UN Guiding Principles on Business and Human Rights (2011)’ and the ‘Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (2008)’ have both emphasized that business enterprises like pharmaceutical companies have human rights responsibilities⁶⁶ in regards to accessibility to medicines⁶⁷.

As mentioned in paragraph 35 of the General Comment No. 17⁶⁸ of CESCR, “intellectual property is a social product and has a social function”. This means that IP authors, such as pharmaceutical companies, are socially obligated to ensure that the innovations are made accessible for the benefit of the public, especially during health emergencies. Prof. Peter K. Yu, while studying the relationship between IPR and Human rights, mentioned that IP and trade are closely related, and the main issue is the strong focus on profit maximization, which prioritizes trade over the social function of IP rights⁶⁹.

Liability of Non-state Actors

The issue of liability of non-state actors such as business enterprises and corporations for violations

⁶² OXFAM, ‘Oxfam update on South African Court Case: South Africa vs. the Drug Giants’, OXFAM, April 2001, available at <https://oxfamlibrary.openrepository.com/bitstream/handle/10546/620381/bn-update-access-to-medicines-south-africa-110401-en.pdf;jsessionid=01261630C8E0DFC5AF648E97216F8A2D?sequence=2>.

⁶³ *Statement on universal and equitable access to vaccines for the coronavirus disease (COVID-19)*, UN Committee on Economic, Social and Cultural Rights (CESCR), E/C.12/2020/2, 15 December 2020, para.6.

⁶⁴ *Ibid*

⁶⁵ Sharifah Sekalala et.al., ‘Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine’, BMJ Global Health, 11 June 2021, p. 5, available at <https://gh.bmj.com/content/6/7/e006169>, accessed on 20 August 2022.

⁶⁶ *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*, 11 August 2008, Published on the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, UN/Doc/A/63/263.

⁶⁷ *Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework*, December 2011, OHCHR, New York and Geneva, p. 13, available at https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf, accessed on 20 March 2022.

⁶⁸ *General Comment No.17: The Rights of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1(c) of the Covenant)*, 12 January 2006, UN Committee on Economic, Social and Cultural Rights (CESCR), E/C.12/GC/17, para 35.

⁶⁹ K Yu. (n 8), pp. 1444-1445.

of human rights is an important aspect of current human rights application discourse. Article 5 of Articles on Responsibilities of State for Internationally Wrongful Act, 2001 mentions that, “the conduct of a person or entity which is not an organ of a state under article 4 but which is empowered by the state to exercise certain elements of governmental authority shall be considered as an act of the state under international law...”⁷⁰. This shows that there has been a shift in the historical and present-day role and responsibilities of corporations when it comes to the question of human rights obligations. The corporations must also look into the ethical and legal obligations in the perpetuation of poverty and inequality.

Human rights bodies have faced many obstacles in holding corporate houses accountable for human rights violations in the past due to a traditional view that only states are the primary actors in respecting, protecting, and fulfilling human rights. Despite the recognition of the direct responsibility of business houses to respect, protect, and fulfill human rights in recent times, the obligation has only been acknowledged as a negative obligation. Hence, the draft articles stress that states must safeguard against human rights violations by third parties including business houses within territory, jurisdiction or the areas within their control⁷¹ i.e., pharmaceutical companies in this case.

Past precedents of temporary waiver and human rights considerations

One of the examples of temporary waivers of IP rights was during the HIV/AIDS endemic in Africa by the UN Sub-Commission. Until 2005, the Sub-Saharan region in Africa, which is home to over 10% of the world's population, has more than 60% or more than 25 million people living with HIV/AIDS⁷². On 17th August 2000, the UN Sub-Commission for the Promotion and Protection of Human Rights in resolution 2000/7 reminded “all governments of the primacy of human rights obligations over economic policies and agreements”⁷³ and went as further as to request all governments to incorporate human rights obligations and principles into their economic policy formulation⁷⁴.

During the HIV/AIDS epidemic of 2005 in Sub-Saharan Africa, the UN Commission on Human Rights stressed for practical action to combat public health emergencies and affirmed that the importance of public health interests in both pharmaceutical and health policies in its 2005/23 resolution⁷⁵. These resolutions gave the world community, along with the developed nations and the pharmaceutical companies, a sense of moral obligation to temporarily reconsider the precedence of human health over the intellectual property right in the event of public health emergencies.

⁷⁰ *Draft Article on Responsibility of States for Internationally Wrongful Acts*, 2001, Supplement No. 10 (A/56/10), art. 5, available at https://legal.un.org/ilc/texts/instruments/english/draft_articles/9_6_2001.pdf.

⁷¹ Obiora C. Okafor, ‘International solidarity and the extraterritorial application of human rights: prospects and challenges’, *Human Rights Council*, A/HRC/50/37, 19 April 2022, para 53, available at <https://documents.un.org/doc/undoc/gen/g22/322/44/pdf/g2232244.pdf?OpenElement>.

⁷² Debrewerk Zewdie, ‘The HIV/AIDS Epidemic in Africa: Implications for Development’, *United Nations Commission on Population and Development United Nations*, New York, 5 April 2005, p. 1-2, available at <https://www.un.org/en/development/desa/population/pdf/commission/2005/keynote/zewdie.pdf>, accessed on 19 July 2023.

⁷³ Intellectual Property rights and Human Rights, *OHCHR, Sub-commission on Human Rights Resolution 2000/7*, 17 August 2000, p.2, para 3, available at https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/E-CN_4-SUB_2-RES-2000-7_Eng.pdf.

⁷⁴ *Ibid* para 4.

⁷⁵ *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria* UN Commission on Human Rights, 15 April 2005, E/CN.4/RES/2005/23.

V. Balancing approach

The discussion on safeguarding intellectual property rights (IPR) in regard to access to healthcare services, such a vaccines and other medical supplies became particularly gained particular relevance during the COVID-19 pandemic, which ultimately exposed the continuous nature of conflict between the goals of public health and the business interests of pharmaceutical companies who hold patent rights. A more balanced approach to ease the tensions between these competing sets of human rights, i.e., IPR and the Human right to health, is necessary. Some of the necessary points to be considered include:

- A. *Right to life and right to health nexus*: Right to life is considered to the most fundamental of all rights, as other rights become unattainable if right to life is not guaranteed⁷⁶. It is true that human rights are interdependent, indivisible, and interrelated⁷⁷. This will mean that violating one set of human rights, such as the right to health, will greatly impact the enjoyment of another set of human rights, including the right to life. Advocates for human rights believe that lifesaving medicines and vaccines, particularly in the context of public health emergencies, must supersede the protection offered under the IPRs. An example of such practice is the UN Sub-Commission on Human Rights resolution during HIV/AIDS pandemic in sub-Saharan Africa which emphasized the right to health over IP rights⁷⁸. These elements were also incorporated in the TRIPS waiver proposal put forth by India and South Africa and were widely supported by people from different fields, including IP experts, former heads of state, celebrities, religious leaders, scientists, health professionals, and the general public who have raised their voices through petitions and letter⁷⁹.
- B. *TRIPS flexibilities in regards to compulsory licensing*: Most countries and primarily the high-income countries who were in opposition to the TRIPS waiver, preferred to stick to existing flexibilities of compulsory licensing under Article 31 and claimed it to be adequate to meet public health challenges as it being one of the most powerful tools under the TRIPS Agreement to further public health concerns while the developing and middle income countries were reluctant to use it.⁸⁰ A compulsory licensing mechanism allows the government to authorize the production of patented goods without the consent of the patent holder if adequate compensation is provided. An example of this is the European Union's willingness to negotiate terms of compulsory licensing under the TRIPS agreement⁸¹. This approach could amount to a balancing approach as it does not entirely disregard the interests of the patent holders⁸² while ensuring the right to health of the general public.

⁷⁶ Kolawole (n 18), p. 96.

⁷⁷ *Vienna Declaration and Program of Action*, The Human Conference on Human Rights in Vienna, 25 June 1993, p. 3, available at <https://www.ohchr.org/sites/default/files/vienna.pdf>.

⁷⁸ OCHR (n 75).

⁷⁹ Alan Rossi Silva et.al., 'Intellectual Property and Global inequality in COVID-19 Vaccines: The struggle for right to health in times of emergency', *International Journal on Human Rights*, August 2021, p. 113, available at <https://sur.conectas.org/wp-content/uploads/2022/05/08-sur-31-eng-alan-rossi-silva-et-al.pdf>, accessed on 2 September 2023.

⁸⁰ Carlos Correa, Reto M. Hitly, 'Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law', *Springer Publication*, Geneva, 2022, pp.74-75, available at https://hepcoalition.org/IMG/pdf/2022_book_accesstomedicinesandvaccines.pdf.

⁸¹ *Urgent trade policy responses to the COVID-19 crisis*, Communication from the European Union, General Council of World Trade Organization, 4 June 2021, WT/GC/231, para 13, available at <https://circabc.europa.eu/rest/download/efa9261f-b5e2-41af-9617-2fb937a8ca42>.

⁸² TRIPS and Health FAQ, 'Compulsory licensing of pharmaceuticals and TRIPS', *WTO*, available at <https://www.wto.org>.

- C. *Voluntary licensing and technology transfer*: Another approach to balancing IP rights and public health needs includes either voluntary licensing, where patent holders allow manufacturers to produce vaccines under certain agreed conditions. One of the examples of the issuance of emergency use authorization is the one given by the British-Swedish vaccine-making company called AstraZeneca. The Serum Institute secured the license in June 2020 from British vaccine maker AstraZeneca to produce vaccines for countries like India, Bangladesh, and Nepal⁸³. The company gave the emergency use authorization of its vaccines to countries such as India, the Dominican Republic, Argentina, Morocco, Mexico, etc.⁸⁴ The company also partnered with Serum Institute of India (SII), which is one of the largest vaccine producers in the world for the supply of vaccine to low and middle-income countries, including the Indian government⁸⁵. Such agreements can promote technology transfer and enhance production capacities in low-income countries. However, these agreements can lack transparency as patent holders have excessive control over the terms and conditions⁸⁶.
- D. *Differential pricing based on economic condition*: Some experts also proposed a mechanism of adjusting the pricing of the vaccines and medical supplies based on the economic condition of a given country by the patent holder or seller. This approach seeks to ensure fair access without undermining the IP rights of pharmaceutical companies. One example of this can be considered when the Government of Nepal entered into a non-disclosure agreement⁸⁷ with the Chinese vaccine manufacturing company, Sinopharm, for the procurement of its vaccines. However, such an arrangement can also have transparency and accountability concerns within a country⁸⁸.
- E. *International Cooperation and assistance*: International mechanisms like the COVAX facilities or other dedicated funds can help to reduce gaps in vaccines and medical supplies distribution. The COVAX facility, co-led by WHO, GAVI, and CEPI, represents a collective measure for addressing global health emergencies without compromising the existing IP frameworks⁸⁹. Similarly, another form of international cooperation was seen in the COVID-19 Technology Access Pool, or C-TAP in short, launched by the World Health Organization (WHO), the government of Costa Rica, and other partners. It aimed at facilitating faster and equitable access to COVID-19 vaccines at affordable prices for people in all countries. C-TAP was

org/english/tratop_e/trips_e/public_health_faq_e.htm.

⁸³ Fraiser Kansteiner, 'UK inspects AstraZeneca vaccine partner's India manufacturing, settling stage for supply boost', *FIERCE Pharma*, 16 Feb 2021, available at <https://www.fiercepharma.com/manufacturing/serum-institute-india-up-for-british-audit-as-astrazeneca-looks-to-boost-covid-19>, accessed on 20 August 2023.

⁸⁴ Press release, 'Serum Institute of India obtain emergency use authorization in India for AstraZeneca's COVID-19 vaccine', *AstraZeneca*, 6 January 2021, available at <https://www.astrazeneca.com/media-centre/press-releases/2021/serum-institute-of-india-obtains-emergency-use-authorisation-in-india-for-astrazenecas-covid-19-vaccine.html#>.

⁸⁵ Ibid

⁸⁶ Prabhash Ranjan, 'The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines', *Observer Research Foundation*, Issue no.456, p. 10, April 2021, available at https://www.orfonline.org/wp-content/uploads/2021/04/ORF_IssueBrief_456_TripsWaiver.pdf, accessed on 19 August 2023.

⁸⁷ A Briefing paper, 'Unprepared and Unlawful: Nepal's Continued Failure to realize the right to health during the COVID-19 pandemic', *International Commission of Jurists (ICJ)*, September 2021, p.31, available at <https://www.icj.org/wp-content/uploads/2021/09/Nepal-Right-to-Health-Publication-2021-ENG.pdf>.

⁸⁸ Prithvi Man Shrestha, 'Nepal sign non-disclosure agreement to buy Chinese Covid-19 Vaccines', *The Kathmandu Post*, Kathmandu, 6 June 2021, available at <https://kathmandupost.com/national/2021/06/06/nepal-signs-non-disclosure-agreement-to-buy-chinese-covid-19-vaccines-but-legal-questions-remain>, accessed on 23 April 2022.

⁸⁹ Muhammad Zaheer Abbas, 'COVID-19 and the global public health: Tiered pricing of pharmaceutical drugs as a price-reducing policy tool', *Journal of Generic Medicine*, vol 17:3, 9 August 2023, p. 116.

endorsed by 45 WHO member states as a response to the global solidarity call of actions⁹⁰. Additionally, Article 2(1) of the ICESCR also obliges states to engage in international cooperation and assistance to realize the right to health⁹¹.

VI. Conclusion and Way forward

Both IP Rights and the human right to health are crucial components of the international human rights law regime and hold, if not equal, but a similar degree of importance. However, during public health emergencies of international concern like the COVID-19 pandemic, the strict enforcement of IP protections may come in conflict with the urgent need to ensure life-saving vaccines and other medical supplies. While IP rights do play a crucial role in promoting innovation and enabling pharmaceutical companies to invest in research and development, a strict application during public health emergencies can lead to a lack of equitable access to health care facilities, particularly for low and middle countries across South Asia and Africa which is a direct threat to enjoyment of right to life. The COVID-19 pandemic emphasized a need for a balanced and rights-based approach which ensures the right to health while also respecting IP rights.

In order to effectively balance IP protections with the universal right to health, particularly during a global health crisis, the following interconnected strategies can be pursued:

- a. Encouraging voluntary licensing agreements, such as a partnership between AstraZeneca and the Serum Institute of India, proved to expand vaccine production and ensure wider access.
- b. In instances where voluntary licenses fail, compulsory licensing under the TRIPS agreement can be considered as one of the legitimate legal tools to protect public health.
- c. Introducing differential pricing based on countries' economic capacities can also promote affordability without compromising scientific innovations.
- d. Global health initiatives like COVAX and C-TAP must be pushed and reformed in line with the obligation enshrined under Article 2(1) of ICESCR.

Looking forward, it is important for the global community to institutionalize the balancing mechanisms within international health care governance systems. By building on lessons learned from COVID-19 and incorporating a balanced and human rights-based approach, future health emergencies can be tackled in a better way. Lastly, the readiness of pharmaceutical companies to respond equitably in future pandemics will be determined by how a proper balance is maintained between the fundamental right to human health and IP rights.



⁹⁰ Initiatives, 'WHO Covid 19 technology access pool', *World Health Organization (WHO)*, May 2020, available at <https://www.who.int/initiatives/covid-19-technology-access-pool>.

⁹¹ ICESCR (n 12), art. 2(1).