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TRIPS Flexibilities and Equitable Access to Medicines in Pandemics: A TWAIL Analysis of HIV/AIDS and COVID-19 Experiences

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ABSTRACT

During pandemics, States require vaccines and medicines on a mass scale, at affordable cost and without delay, to combat infectious diseases. Vaccines and medicines, however, are subject to twenty-year patent rights. The patent system under the TRIPS Agreement restricts the production and export of low-cost generic versions of new medicines. Most low- and middle-income countries (LMICs) cannot afford expensive patented medicines. They also lack the resources and infrastructure to produce generic medicines and consequently depend heavily on pharmaceutical imports. Yet they are also unable to use compulsory licences to import medicines, because Article 31(f) of the TRIPS Agreement restricts generic-producing nations from exporting to them: it allows those nations to use compulsory licences predominantly for the supply of their own domestic market. Article 31bis, which implements paragraph 6 of the Doha Declaration, permits export and import under strict and complex conditions, and there has been only one successful use of the system it codifies, Rwanda's import of HIV medicines from Canada under the 2003 waiver. Moreover, the patent system cannot be viewed in isolation: the patent–trade secret duopoly extends protection beyond the twenty-year patent term. TRIPS flexibilities therefore operate as strategies that maintain the disparities in negotiating power between pharmaceutical companies and LMICs, and thus the status quo. HIV/AIDS and COVID-19 are the two principal pandemics to have occurred since the adoption of the TRIPS Agreement. Drawing on a comparative analysis of these two pandemics, this paper examines a central question: why does reliance solely on the public health-related TRIPS flexibilities not appear to be a sufficient means of ensuring fair and equitable access to medicines in pandemics? It argues that the TRIPS flexibilities are not sufficient to ensure fair and equitable access to medicines, particularly in pandemics, and proposes legal mechanisms to mitigate the adverse consequences arising from the limitations of the TRIPS flexibilities in addressing future pandemics.

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I. INTRODUCTION

Humanity has celebrated its technological, material and intellectual achievements, yet it is not free from stress, fear and pain. For centuries, States have fought one another to recover past glories. The powerful States, in terms of economy, wealth and political influence within international alliances, control the international legal order.¹ Poor and developing countries struggle with Eurocentric² international law and its imperialistic effects.³ As of June 2026, the global community continues to grapple with the staggering impact of the COVID-19 pandemic, with some 779 million⁴ reported cases and over 7.1 million⁵ recorded deaths. This crisis has been nothing short of a war: not a conventional war between States, but a battle between humanity and SARS-CoV-2,⁶ the virus that causes COVID-19. Pandemics of this kind are a form of warfare in their own right; transnational or global health emergencies, or Public Health Emergencies of International Concern (PHEIC),⁷ pose threats as serious and devastating as any armed conflict.

Before COVID-19, the most severe pandemic of the past century was the 1918–1920 influenza pandemic, commonly referred to as the Spanish flu.⁸ That outbreak, just over a hundred years ago, remains one of the most devastating global health crises in modern history. It was caused

¹ B.S. Chimni, *International Institutions Today: An Imperial Global State in the Making*, 15 EUR. J. INT'L L. 1 (2004), <https://doi.org/10.1093/ejil/15.1.1>, also available at <https://ssrn.com/abstract=803817>.

² Anne-Charlotte Martineau, *Overcoming Eurocentrism? Global History and the Oxford Handbook of the History of International Law*, 25 EUR. J. INT'L L. 329 (2014), <https://doi.org/10.1093/ejil/chu017>.

³ SUNDHYA PAHUJA, *DECOLONISING INTERNATIONAL LAW: DEVELOPMENT, ECONOMIC GROWTH AND THE POLITICS OF UNIVERSALITY* 4 (2011), <https://www.cambridge.org/9780521199032>.

⁴ WORLD HEALTH ORGANIZATION, *COVID-19 Cases*, WHO COVID-19 Dashboard, <https://data.who.int/dashboards/covid19/cases?n=o>.

⁵ WORLD HEALTH ORGANIZATION, *COVID-19 Deaths*, WHO COVID-19 Dashboard, <https://data.who.int/dashboards/covid19/deaths?n=o>. A separate WHO estimate, published on 5 May 2022, put the excess deaths associated with the COVID-19 pandemic in 2020 and 2021 at 14.9 million. WORLD HEALTH ORGANIZATION, *14.9 Million Excess Deaths Were Associated with the COVID-19 Pandemic in 2020 and 2021* (May 5, 2022), <https://www.who.int/news/item/05-05-2022-14.9-million-excess-deaths-were-associated-with-the-covid-19-pandemic-in-2020-and-2021>.

⁶ Stephan Ludwig & Alexander Zarbock, *Coronaviruses and SARS-CoV-2: A Brief Overview*, 131 ANESTHESIA & ANALGESIA 93 (2020), <https://doi.org/10.1213/ANE.0000000000004845>.

⁷ A public health emergency of international concern (PHEIC) is defined in Article 1 of the International Health Regulations (2005), adopted by the World Health Assembly, as “an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.” WORLD HEALTH ORGANIZATION, *International Health Regulations* (2005) art. 1 (3d ed. 2016).

⁸ C. Niranjan Rao, *Pandemic and the Patent System*, 56 ECON. & POL. WKLY., no. 44, Oct. 30, 2021, <https://www.epw.in/journal/2021/44/commentary/pandemic-and-patent-system.html>.

by the H1N1 subtype of the influenza A virus.⁹ Between 50 and 100 million people are thought to have died.¹⁰ Because the pandemic spread during the First World War, the range of that estimate is wide and uncertain.¹¹ Since shipping was then the main mode of transport, the 1918 pandemic travelled slowly across the world,¹² whereas COVID-19 spread across the world in a relatively short time because air travel now predominates. Between these two pandemics, several epidemics and pandemics struck various parts of the world, such as the Asian flu of 1957,¹³ the Hong Kong flu of 1968,¹⁴ the HIV/AIDS pandemic (from 1981 to the present)¹⁵ and the swine flu of 2009.¹⁶ Among them, the HIV/AIDS global epidemic or pandemic¹⁷ has been the most dangerous. In 2024, approximately 630,000 people (within a range of 490,000 to 820,000) died worldwide from HIV-related illnesses.¹⁸ The African region is the most affected.¹⁹

To address such PHEICs effectively, States require access to mass vaccination, existing medicines and future medical treatments, such as therapeutics, at affordable and reasonable cost

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ Claire Jackson, *History Lessons: The Asian Flu Pandemic*, 59 BRIT. J. GEN. PRAC. 622 (2009), <https://doi.org/10.3399/bjgp09X453882>.

¹⁴ Mark Honigsbaum, *Revisiting the 1957 and 1968 Influenza Pandemics*, 395 LANCET 1824 (2020), [https://doi.org/10.1016/S0140-6736\(20\)31201-0](https://doi.org/10.1016/S0140-6736(20)31201-0).

¹⁵ WORLD HEALTH ORGANIZATION, *HIV Data and Statistics*, <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/strategic-information/hiv-data-and-statistics>; see also Chris Beyrer, *A Pandemic Anniversary: 40 Years of HIV/AIDS*, 397 LANCET 2142 (2021), [https://doi.org/10.1016/S0140-6736\(21\)01167-3](https://doi.org/10.1016/S0140-6736(21)01167-3).

¹⁶ WORLD HEALTH ORGANIZATION, *The Burden of Influenza* (Mar. 30, 2024), <https://www.who.int/news-room/feature-stories/detail/the-burden-of-influenza>.

¹⁷ WHO generally avoids calling HIV/AIDS a “pandemic”: its HIV fact sheets and data pages consistently describe HIV as a global epidemic or a major global public health issue. See WORLD HEALTH ORGANIZATION, *HIV Data and Statistics* (July 2025), <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/strategic-information/hiv-data-and-statistics>. The U.S. Centers for Disease Control and Prevention has, however, occasionally used “pandemic” when discussing HIV globally: its Vital Signs report on the impact of PEPFAR describes “the HIV pandemic” in praising the scale-up of treatment, while concluding that PEPFAR and CDC have “dramatically altered the course of the HIV epidemic” and emphasising the goal of ending HIV as a global public health threat. See CTRS. FOR DISEASE CONTROL & PREVENTION, *Eliminating HIV as a Global Health Threat: Vital Signs* (Jan. 31, 2025), <https://www.cdc.gov/global-hiv-tb/php/globalhiv/vitalsigns.html>. CDC’s language is thus mixed: it uses “HIV pandemic” in narrative contexts but also frames HIV as an epidemic and a global public health crisis. UNAIDS, by contrast, routinely uses pandemic terminology for HIV/AIDS: its 2025 Global AIDS Update refers to “the challenges of the HIV pandemic today”, and its 2024 report web pages call AIDS “the world’s deadliest pandemic”. See UNAIDS, *AIDS, Crisis and the Power to Transform: UNAIDS Global AIDS Update 2025*, UNAIDS/JC3153 (July 2025), https://www.unaids.org/sites/default/files/2025-07/2025-global-aids-update-JC3153_en.pdf; see also UNAIDS, *The Urgency of Now: AIDS at a Crossroads: 2024 Global AIDS Update* (2024), <https://www.unaids.org/en/resources/documents/2024/global-aids-update-2024>. Across public health, epidemiology, medical anthropology, sociology, history and global health, many scholars in both the Global North and the Global South also refer to HIV/AIDS as a “pandemic”. Because a clear distinction between a “global” or “multi-continent” epidemic and a “pandemic” remains difficult to draw, this paper treats HIV/AIDS as a pandemic.

¹⁸ WORLD HEALTH ORGANIZATION, *HIV Data and Statistics*, *supra* note 15.

¹⁹ *Id.*

and on an equitable basis.²⁰ In other words, epidemics and pandemics cannot be overcome without guaranteeing fair and equitable access to essential medicines for all individuals, regardless of their social status or geographical location.²¹ During the HIV/AIDS and COVID-19 pandemics, pharmaceutical patents under the TRIPS Agreement remained a monumental obstacle to fair and equitable access to essential medicines, particularly for low- and middle-income countries (LMICs), where the effects are most severe.²² The TRIPS Agreement makes patent protection mandatory for both products and processes in all fields of technology, including pharmaceuticals.²³ Vaccines and medicines are therefore also subject to twenty-year patent rights.

The patent system under the TRIPS Agreement restricts the production and export of low-cost generic versions of new medicines.²⁴ Most LMICs cannot afford expensive patented medicines.²⁵ They also lack the resources and infrastructure to produce generic medicines,²⁶ and consequently depend heavily on pharmaceutical imports. Yet they are also unable to use compulsory licences to import medicines, because Article 31(f) of the TRIPS Agreement restricts generic-producing nations from exporting to them.²⁷ Article 31(f) allows generic-producing States to use compulsory licences predominantly for the supply of their own domestic

²⁰ WORLD HEALTH ORGANIZATION, *Fair Allocation Mechanism for COVID-19 Vaccines Through the COVAX Facility* (Sept. 9, 2020), <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility> (last visited Apr. 6, 2025); see also Sam Halabi & Lawrence Gostin, *Realizing the World Health Organization's Constitutional Mission: Equitably and Everywhere*, 2025 U. CHI. LEGAL F. 227, <https://chicagounbound.uchicago.edu/uclf/vol2025/iss1/7>; Yunhui Xiang, Guokang Sun, Pinpin Xiang, Jiangtao Hu, Lvbo Tian, Qin Zhang, Junxian Wang & Chunbao Xie, *Confronting the Known Unknown: Historical Lessons and Future Strategies for Disease X*, 14 FRONTIERS PUB. HEALTH 1833807 (2026), <https://doi.org/10.3389/fpubh.2026.1833807>.

²¹ WORLD HEALTH ORGANIZATION, *Medicines Affordability and Pricing*, Health Products Policy and Standards, <https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/affordability-pricing>.

²² Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSPS. 3 (2013), <https://doi.org/10.1257/jep.27.1.3>, <http://www.jstor.org/stable/41825459>; OXFAM, *TRIPS and Public Health: The Next Battle* (Oxfam Briefing Paper No. 15, 2001), <https://policy-practice.oxfam.org/resources/trips-and-public-health-the-next-battle-115047/>; Michael J. Cavaliere, *Ensuring Developing Countries' Access to COVID-19 Vaccines: Why the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities Fail and the Current International Framework Needs Immediate Reform*, 35 N.Y. INT'L L. REV. 49 (2022), <https://nyilrdotcom.wordpress.com/wp-content/uploads/2023/08/nyilr-issue-vol.-35-no.-1-spring-2022.pdf>; Valbona Muzaka, *The Pharmaceutical Patent System and Access to Medicines*, in HANDBOOK ON THE POLITICAL ECONOMY OF HEALTH SYSTEMS 380 (2023), <https://doi.org/10.4337/9781800885066.00030>, <https://www.elgaronline.com/edcollchap/book/9781800885066/book-part-9781800885066-30.xml>.

²³ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]. Article 27(1) provides that, “[s]ubject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”

²⁴ See sources cited *supra* note 22.

²⁵ See sources cited *supra* note 22.

²⁶ See sources cited *supra* note 22.

²⁷ See sources cited *supra* note 22.

market.²⁸ Article 31bis, which implements paragraph 6 of the Doha Declaration, permits export and import under strict and complex conditions.²⁹ There has been only one completed use of the export mechanism now embodied in Article 31bis, namely Canada's supply of HIV medicines to Rwanda.³⁰ Moreover, the patent system cannot be viewed in isolation. The patent–trade secret duopoly extends protection beyond the twenty-year patent term.³¹ TRIPS flexibilities therefore operate as strategies that maintain the disparities in negotiating power between pharmaceutical companies and LMICs, and thus the status quo.

HIV/AIDS and COVID-19 are the two principal pandemics to have occurred since the adoption of the TRIPS Agreement. Drawing on a comparative analysis of these two pandemics, this paper examines a central question: why does reliance solely on the public health-related TRIPS flexibilities not appear to be a sufficient means of ensuring fair and equitable access to medicines in pandemics? Through this question, the paper argues that the TRIPS flexibilities are not sufficient to ensure fair and equitable access to medicines, particularly in pandemics. It therefore proposes legal mechanisms to mitigate the adverse consequences arising from the limitations of the TRIPS flexibilities in addressing future pandemics.

The answer to this central research question proceeds in five parts. To lay the foundation, Part II examines the “flexibilities” relating to access to medicines under the TRIPS Agreement. Part III examines the failure of the TRIPS flexibilities during both the HIV/AIDS and COVID-19 pandemics, which substantiates the main claim of this paper: that the flexibilities do not appear to be a sufficient means of ensuring fair and equitable access to medicines in pandemics. Part IV proposes legal mechanisms to mitigate the adverse consequences arising from the limitations of the TRIPS flexibilities in addressing future pandemics. Part V concludes that legal mechanisms alone are insufficient to address these challenges; their effective implementation requires sustained resistance, political will, and the continued advocacy of developing countries, civil society and affected communities.

²⁸ TRIPS Agreement, *supra* note 23, art. 31(f) (“any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”).

²⁹ *Id.* art. 31bis(1) (“The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.”).

³⁰ Nicholas G. Vincent, *Trip-ing Up: The Failure of TRIPS Article 31bis*, 24 GONZ. J. INT’L L. 1 (2020), <https://access.heinonline.com/HOL/LandingPage?handle=hein.journals/gjil24&div=3&id=&page=>.

³¹ Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dutfield, *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81 CAMBRIDGE L.J. 384, 396 (2022), <https://doi.org/10.1017/S0008197322000241>.

II. TRIPS FLEXIBILITIES: CONCEPT AND TYPES

Article 27 of the TRIPS Agreement mandates patent protection for both products and processes in all fields of technology, including pharmaceuticals.³² Although intended to encourage innovation, the introduction of product patents in pharmaceuticals has significantly restricted access to medicines in LMICs, especially for infectious diseases.³³ Patent-holding companies often lack incentives to serve these markets, and generic manufacturers are blocked from early entry, reducing the availability of affordable medicines.³⁴ The patent system under the TRIPS Agreement nevertheless carries numerous flexibilities related to public health.

The TRIPS Agreement does not define “flexibilities”. The term refers to the variety of legislative options available under the Agreement.³⁵ In early studies and reports, “flexibilities” referred to “room for manoeuvre”, “margins for freedom” or “margins for discretion”, and “safeguards”.³⁶ The term covers possible variations in the manner in which the provisions of the TRIPS Agreement are interpreted and implemented; “flexibilities” are, in this sense, a constructive ambiguity that preserves policy space.³⁷ The word “flexibility” is used in the preamble,³⁸ Article 31bis(5)³⁹ and Article 66(1)⁴⁰ of the TRIPS Agreement. It came into wide global use, however, during the HIV/AIDS pandemic, when the patent system under TRIPS

³² TRIPS Agreement, *supra* note 23, art. 27(1).

³³ Jayashree Watal & Rong Dai, *Product Patents and Access to Innovative Medicines in a Post-TRIPS Era* (July 17, 2019), <https://ssrn.com/abstract=3394851>.

³⁴ See sources cited *supra* notes 22, 30, 31 and 33.

³⁵ WORLD INTELLECTUAL PROPERTY ORGANIZATION, Standing Committee on the Law of Patents, *Comments Made by Members and Observers of the SCP on Documents SCP/13/3, SCP/14/7 and SCP/15/3* (15th Sess., Oct. 11–15, 2010) (excerpting the report of the session, SCP/15/6), https://www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_7_comments.pdf.

³⁶ WORLD INTELLECTUAL PROPERTY ORGANIZATION, Committee on Development and Intellectual Property, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, at 10–25, CDIP/5/4 Rev. (Aug. 18, 2010), https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4_rev-main1.pdf.

³⁷ Carlos M. Correa, *Interpreting the Flexibilities Under the TRIPS Agreement*, in ACCESS TO MEDICINES AND VACCINES: IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUAL PROPERTY LAW 1 (Carlos M. Correa & Reto M. Hilty eds., 2022), https://doi.org/10.1007/978-3-030-83114-1_1.

³⁸ TRIPS Agreement, *supra* note 23, pmb1. (“Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base”).

³⁹ *Id.* art. 31bis(5). The amendment, adopted by the General Council on 6 December 2005 and in force since 23 January 2017, inserted Article 31bis, an Annex and an Appendix to the Annex into the TRIPS Agreement. See GENERAL COUNCIL, *Amendment of the TRIPS Agreement: Decision of 6 December 2005*, WT/L/641 (Dec. 8, 2005). Article 31bis(5) provides: “This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation.”

⁴⁰ TRIPS Agreement, *supra* note 23, art. 66(1) (“In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65.”).

obstructed fair and equitable access to medicines for LMICs, especially in Africa, as reflected in the Doha Ministerial Declaration of 2001,⁴¹ paragraph 17 of which announced a separate declaration on the TRIPS Agreement and public health.⁴²

The idea of “TRIPS flexibilities” has featured in a wealth of literature since the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, particularly (though not exclusively) in relation to access to medicines.⁴³ It has also been taken up in the work of UN agencies,⁴⁴ the Human Rights Council (HRC),⁴⁵ the World Trade Organization (WTO),⁴⁶ the World Health Organization (WHO)⁴⁷ and the World Intellectual Property Organization (WIPO),⁴⁸ as well as in the report of the UN Secretary-General’s High-Level Panel on Access to Medicines.⁴⁹ To address public health, particularly access to medicines, WHO, WIPO and the WTO stepped up their trilateral cooperation in 2009; their joint study, first published in 2013 and updated in 2020, explores how countries can use TRIPS flexibilities to improve access to medicines, particularly during public health emergencies, which remains the central aim of the initiative.⁵⁰

⁴¹ WORLD TRADE ORGANIZATION, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1 (Nov. 20, 2001) [hereinafter Doha Ministerial Declaration], https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

⁴² *Id.* ¶¶ 17, 25. Paragraph 17 reads: “We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.” Paragraph 25, on the interaction between trade and competition policy, provides that “[f]ull account shall be taken of the needs of developing and least-developed country participants and appropriate flexibility provided to address them.” The separate declaration contains the language of flexibility for public health: “we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” WORLD TRADE ORGANIZATION, Declaration on the TRIPS Agreement and Public Health ¶ 4, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

⁴³ GERMÁN VELÁSQUEZ, CARLOS M. CORREA & VITOR IDO, INTELLECTUAL PROPERTY, HUMAN RIGHTS AND ACCESS TO MEDICINES: A SELECTED AND ANNOTATED BIBLIOGRAPHY (South Centre, 3d ed. 2020), <https://www.southcentre.int/book-by-the-south-centre-2020/#more-14014>.

⁴⁴ One of the first studies on TRIPS flexibilities was published by UNCTAD in 1996. See U.N. CONFERENCE ON TRADE AND DEVELOPMENT, *The TRIPS Agreement and Developing Countries*, UNCTAD/ITE/1 (1996), https://unctad.org/system/files/official-document/ite1_en.pdf.

⁴⁵ Jennifer Anna Sellin, *Does One Size Fit All? Patents, the Right to Health and Access to Medicines*, 62 NETH. INT’L L. REV. 445 (2015), <https://doi.org/10.1007/s40802-015-0047-5>.

⁴⁶ WORLD TRADE ORGANIZATION, *TRIPS and Public Health: “Paragraph 6” System: Notifications by Importing WTO Members*, http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm.

⁴⁷ WORLD HEALTH ORGANIZATION, *WHO, WIPO, WTO Launch Updated Study on Access to Medical Technologies and Innovation* (July 29, 2020), <https://www.who.int/news/item/29-07-2020-who-wipo-wto-launch-updated-study-on-access-to-medical-technologies-and-innovation>.

⁴⁸ WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Patent Related Flexibilities*, *supra* note 36, at 11.

⁴⁹ U.N. SECRETARY-GENERAL’S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES, *Promoting Innovation and Access to Health Technologies: Final Report* (Sept. 2016), <https://www.unsgaccessmeds.org/final-report/>.

⁵⁰ WHO, WIPO & WTO, *Trilateral Cooperation on Public Health, IP and Trade*, https://www.wipo.int/en/web/global-health/trilateral_cooperation; see also WORLD HEALTH ORGANIZATION, WORLD TRADE ORGANIZATION & WORLD INTELLECTUAL PROPERTY ORGANIZATION, *An Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic* 1–31 (2d update, May 2023).

The TRIPS Agreement contains various kinds of “flexibilities”.⁵¹ Some concern the scope and complexity of the substantive rights that the Agreement recognises; others concern the means by which those rights may be put into practice. A document prepared for the fifth session of WIPO’s Committee on Development and Intellectual Property (CDIP), issued in revised form on 18 August 2010, classified patent-related flexibilities under the TRIPS Agreement into four categories according to their application and purpose.⁵² WIPO’s Database on Flexibilities in the Intellectual Property System identifies fourteen types of flexibility related to access to medicines.⁵³ The report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines⁵⁴ discusses seven flexibilities, which are among those commonly identified by WIPO. Beyond these bodies, the South Centre⁵⁵ provides an exhaustive list of seventeen⁵⁶ types of flexibility, and Health Action International (HAI)⁵⁷ identifies eight⁵⁸ TRIPS flexibilities related to public health.

The exhaustive list of seventeen public health-related flexibilities provided by the South Centre (Development, Innovation and Intellectual Property Programme) includes all the flexibilities listed in the documents and literature mentioned above. They are: (i) flexibility in the choice of patentability criteria, including for chemical entities and biologics; (ii) compulsory licensing; (iii) government use authorisation; (iv) flexibility in the implementation of the Article 31bis amendment to the TRIPS Agreement to address access to medicines for countries lacking manufacturing capacity (the paragraph 6 issue under the Doha Declaration); (v) flexibility in test data protection; (vi) avoidance of TRIPS-plus provisions and policies, including extension of the patent term, data exclusivity, second-use patents and border measures; (vii) mitigating

⁵¹ See WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Patent Related Flexibilities*, *supra* note 36; see also Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* (South Centre & World Health Organization, 2006), <https://iris.who.int/handle/10665/43503>.

⁵² WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Patent Related Flexibilities*, *supra* note 36, at 12–28.

⁵³ WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Database on Flexibilities in the Intellectual Property System*, <https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html>; see also WORLD INTELLECTUAL PROPERTY ORGANIZATION, Committee on Development and Intellectual Property, *Revised Proposal for a Mechanism for Updating the Database on Flexibilities*, CDIP/18/5 (18th Sess., Oct. 31–Nov. 4, 2016), https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_18/cdip_18_5.pdf.

⁵⁴ U.N. SECRETARY-GENERAL’S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES, *supra* note 49 (final report dated Sept. 14, 2016).

⁵⁵ The South Centre is an intergovernmental policy research organisation of developing countries and has done substantial research on pharmaceutical patents and access to medicines. It sets out an exhaustive list of seventeen flexibilities.

⁵⁶ SOUTH CENTRE, *A Public Health Approach to Intellectual Property Rights: Public Health Related Flexibilities in the TRIPS Agreement* (2018), <https://ipaccessmeds.southcentre.int/wp-content/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf>.

⁵⁷ Health Action International (HAI) was founded in 1981 by a group of medicine policy experts to counter the rapidly increasing influence of the pharmaceutical industry.

⁵⁸ HEALTH ACTION INTERNATIONAL, *TRIPS Flexibilities and Access to Medicines: A European Approach* (Brochure, Dec. 13, 2018), <https://haiweb.org/publication/access-to-medicines/>.

the implementation or effects of TRIPS-plus provisions; (viii) special TRIPS flexibilities (including exemptions) for LDCs; (ix) parallel importation; (x) pre-grant and post-grant patent opposition, including the procedures to facilitate them; (xi) use of competition principles and law to address misuse of patents; (xii) the Bolar exception; (xiii) the experimentation exception; (xiv) disclosure requirements, particularly for biologics; (xv) infringement by equivalence; (xvi) provisional and permanent injunctions; and (xvii) flexibilities in the enforcement of IP, such as reversal of the burden of proof, determination of damages and border measures, which, if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines.

Many researchers also suggest that terms such as *ordre public*, “reasonable”, “unreasonably”, “justifiably”, “public interest”, “morality”, “socio-economic development”, “public health and nutrition” and “transitional arrangements”, and phrases such as “to prevent the abuse of intellectual property rights by right holders”, “to the mutual advantage of producers and users” and “to a balance of rights and obligations”, may also fall within the purview of flexibilities, as these terms and phrases have been interpreted by multiple researchers.⁵⁹

A comprehensive examination of every flexibility contained in the TRIPS Agreement is therefore beyond the scope of this paper. Although each flexibility plays a significant role in safeguarding public health, its effectiveness ultimately depends on timely and meaningful implementation, particularly in a pandemic. Accordingly, this paper does not attempt an exhaustive analysis of the TRIPS flexibilities. It aims instead to substantiate its central argument that the public health-related flexibilities under the TRIPS Agreement failed to secure fair and equitable access to medicines during the two principal pandemics of the period since the Agreement entered into force: HIV/AIDS and COVID-19. The experience of these two pandemics reveals significant shortcomings in the practical operation of the TRIPS flexibilities and raises serious concerns about their capacity to respond effectively to future pandemics.

III. FAILURE OF TRIPS FLEXIBILITIES IN ENSURING FAIR AND EQUITABLE ACCESS TO MEDICINES IN THE HIV/AIDS AND COVID-19 PANDEMICS

The “flexibilities” serve public policy objectives, particularly public health. In the interest of public health they are vital, because they appear to address the challenges that LMICs face in putting in place policies that would increase the accessibility and affordability of essential medicines on an equitable basis. Several reports (discussed below), however, suggest that

⁵⁹ Correa, *supra* note 37; see also Khorsed Zaman, *The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence*, 13 EUR. J. RISK REGUL. 295 (2022), <https://doi.org/10.1017/err.2021.60>.

TRIPS flexibilities are merely strategies that maintain the disparities in negotiating power between pharmaceutical companies and LMICs and thus perpetuate the status quo.⁶⁰ The following arguments substantiate the claim that the flexibilities failed to secure fair and equitable access to essential medicines during HIV/AIDS and COVID-19, the two principal pandemics since the TRIPS Agreement entered into force.

A. HIV/AIDS pandemic and the failure of TRIPS flexibilities

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) constitute a global epidemic or pandemic⁶¹ and remain among the major challenges to public health worldwide.⁶² AIDS is the most advanced stage of HIV infection.⁶³ The virus attacks the body's white blood cells, weakening the immune system and leaving a person more vulnerable to other illnesses such as tuberculosis (TB), cryptococcal meningitis, mpox, hepatitis B and hepatitis C, and to some cancers, such as lymphomas and Kaposi's sarcoma.⁶⁴ Since the start of the epidemic, 44.1 million people (37.6 million–53.4 million) have died from AIDS-related illnesses.⁶⁵ At the end of 2024, there were 40.8 million (37.0 million–45.6 million) people living with HIV worldwide, 65% of them in the WHO African Region.⁶⁶ Approximately 630,000 (490,000–820,000) people died from AIDS-related illnesses worldwide in 2024, compared with 2.1 million (1.6 million–2.7 million) in 2004 and 1.4 million (1.1 million–1.8 million) in 2010.⁶⁷ Given this scale, the U.S. Centers for Disease Control and Prevention (CDC) occasionally, and UNAIDS routinely, use “pandemic” terminology for HIV/AIDS.⁶⁸

In the late 1990s and early 2000s, just one in every thousand people living with HIV in Africa could access treatment.⁶⁹ Antiretroviral (ARV) medicines, the primary treatment for HIV/AIDS, were supplied mainly by the originator patent-holding companies and cost an overwhelming

⁶⁰ See sources cited *supra* notes 22, 30, 31 and 33.

⁶¹ See *supra* note 17.

⁶² CTRS. FOR DISEASE CONTROL & PREVENTION, *The Global HIV and AIDS Epidemic, 2001*, 50 MORBIDITY & MORTALITY WKLY. REP. 434 (2001), <http://www.jstor.org/stable/24830507>.

⁶³ NAT'L INSTS. OF HEALTH, *The Stages of HIV Infection*, HIVinfo (last reviewed Mar. 31, 2025), <https://hivinfo.nih.gov/understanding-hiv/fact-sheets/stages-hiv-infection> (last visited Aug. 31, 2025).

⁶⁴ WORLD HEALTH ORGANIZATION, *HIV and AIDS: Fact Sheet* (July 15, 2025), <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>.

⁶⁵ UNAIDS, *2025 Global HIV Factsheet* (July 2025), https://www.unaids.org/sites/default/files/2025-07/2025_Global_HIV_Factsheet_en.pdf.

⁶⁶ WORLD HEALTH ORGANIZATION, *HIV and AIDS*, *supra* note 64; UNAIDS, *2025 Global HIV Factsheet*, *supra* note 65.

⁶⁷ UNAIDS, *2025 Global HIV Factsheet*, *supra* note 65, at 2.

⁶⁸ See *supra* note 17.

⁶⁹ Barton Gellman, *Death Watch, Part 5: An Unequal Calculus of Life and Death: As Millions Perished in Pandemic, Firms Debated Access to Drugs*, WASH. POST (2000); see also Ellen 't Hoen, Jonathan Berger, Alexandra Calmy & Suerie Moon, *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14 J. INT'L AIDS SOC'Y 15 (2011), <https://doi.org/10.1186/1758-2652-14-15>, <https://pmc.ncbi.nlm.nih.gov/articles/PMC3078828/>.

US\$10,000–15,000 per patient per year.⁷⁰ By requiring all governments to provide patent terms of at least twenty years,⁷¹ the TRIPS Agreement shields pharmaceutical companies from generic competition globally and obstructs fair and equitable access to medicines.⁷² Critics argued that the large originator pharmaceutical companies (“Big pharma”)⁷³ asserted their patent rights at the expense of the right to health, which in a pandemic becomes a matter of the right to life. During the HIV/AIDS pandemic, other diseases such as tuberculosis and malaria also posed serious threats to developing countries.⁷⁴ Many of the newer essential medicines for HIV/AIDS were under patent.⁷⁵ Most developing countries still lack the capacity to manufacture medicines and rely mainly on imports from developed countries or from developing countries such as India and China. In 1997, South Africa authorised the parallel importation of patented medicines, including HIV treatments, by amending its Medicines and Related Substances Control Act.⁷⁶ In response, in February 1998, thirty-nine pharmaceutical companies and their trade association, the Pharmaceutical Manufacturers’ Association of South Africa, sued South Africa’s newly democratic, post-apartheid government, challenging the 1997 amendments, which were intended to improve access to affordable medicines.⁷⁷ The companies argued that the amendments were unconstitutional and violated the TRIPS Agreement.

⁷⁰ Carmen Pérez-Casas, Cécile Macé, Daniel Berman & Julia Double, *Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries* (Médecins Sans Frontières, 2001), https://utw.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW1_ENG_2001.pdf.

⁷¹ TRIPS Agreement, *supra* note 23, art. 33 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

⁷² See sources cited *supra* notes 22, 30, 31, 33 and 69.

⁷³ The term “big pharma” describes the world’s fifteen largest pharmaceutical corporations, namely Pfizer (US), Johnson & Johnson (US), Bayer (Germany), Roche (Switzerland), Novartis (Switzerland), GlaxoSmithKline (UK), Sanofi-Aventis (France), AstraZeneca (UK/Sweden), Abbott Laboratories (US), Merck & Co. (US), Bristol-Myers Squibb (US), Eli Lilly & Company (US), Boehringer Ingelheim (Germany), Takeda Pharmaceutical Co. (Japan) and Amgen (US), which dominate the global pharmaceutical economy. Together they control 66% of the global drug market. Of the remaining 34%, around 24% is held by biotechnology firms affiliated with these same companies, while only 10% belongs to independent generic manufacturers. See POKU ADUSEI, PATENTING OF PHARMACEUTICALS AND DEVELOPMENT IN SUB-SAHARAN AFRICA: LAWS, INSTITUTIONS, PRACTICES, AND POLITICS 7 (2013), <https://doi.org/10.1007/978-3-642-32515-1>.

⁷⁴ WORLD HEALTH ORGANIZATION, *State of Inequality: HIV, Tuberculosis and Malaria* (2021), https://www.who.int/data/inequality-monitor/publications/report_2021_hiv_tb_malaria.

⁷⁵ P. Boulet, J. Perriens & F. Renaud-Théry, *Patent Situation of HIV/AIDS-Related Drugs in 80 Countries* (WHO & UNAIDS, Jan. 2000), <https://allafrica.com/download/resource/main/main/idatcs/00010255:568cec5a62e0523319d4f63a4b4dfa89.pdf>; see also MÉDECINS SANS FRONTIÈRES, *Untangling the Web of Antiretroviral Price Reductions* (15th ed. 2012), <https://www.msf.org/untangling-web-antiretroviral-price-reductions-15th-edition>.

⁷⁶ Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.), published in the Government Gazette on Dec. 12, 1997.

⁷⁷ OXFAM, *South Africa vs. the Drug Giants: A Challenge to Affordable Medicines* (Oxfam Briefing Note, Feb. 2001), <https://oxfamilibrary.openrepository.com/bitstream/handle/10546/620381/bn-access-to-medicines-south-africa-010201-en.pdf?sequence=1>. The briefing further notes that among the thirty-nine companies in the case were five of the leading pharmaceutical firms in the HIV/AIDS sector: GlaxoSmithKline, Merck & Co., Bristol-Myers Squibb, Roche and Boehringer Ingelheim. In 2000, the global sales of these companies exceeded three times the South African government’s entire national budget, and their profits were nearly double the government’s combined spending on education, health and welfare.

The lawsuit, however, dealt the pharmaceutical companies a serious public relations blow.⁷⁸ Although they initially had the support of the European Commission and the United States, which threatened sanctions and withheld trade benefits, the international public pressure over their challenge to a developing country's medicines law was so strong, and their legal position so widely criticised, that they unconditionally dropped the case in April 2001.⁷⁹ The world was horrified by what came to be seen as "Big Pharma versus Nelson Mandela".⁸⁰ Because developed countries had themselves long used compulsory licensing regularly, a meeting on "compulsory licensing"⁸¹ of HIV drugs was organised at the United Nations in Geneva in 1999 by a variety of non-state actors, including NGOs and AIDS campaigners. Canada, for instance, issued 613 compulsory licences to produce or import generic drugs between 1969 and 1992, before changing its system under the North American Free Trade Agreement.⁸²

Growing dissatisfaction over the impact of the TRIPS Agreement on public health came to a head at the 1999 WTO Ministerial Conference in Seattle, where there were calls to "humanize the trade agreements".⁸³ Between the collapse of the Seattle Conference and the adoption of the Doha Declaration in 2001, several significant events deeply influenced intellectual property regulation and access to medicines. Developing countries leading the delivery of ARV treatment began to feel the impact of pharmaceutical patents on HIV/AIDS medicines. In countries such as Thailand and Brazil, patents greatly restricted the ability to manufacture cheaper generics legally, with heavy consequences for public health budgets.⁸⁴ At the same time, like many other developing countries, Brazil and Thailand faced intense pressure from high-income countries

⁷⁸ Neil A. Lewis, *U.S. Industry to Drop AIDS Drug Lawsuit Against South Africa*, N.Y. TIMES, Sept. 10, 1999, at A3; see also William W. Fisher III & Cyril P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy* 8–9 (Harvard Law School, 2005), <https://dash.harvard.edu/server/api/core/bitstreams/7312037d-fc02-6bd4-e053-0100007fdf3b/content>.

⁷⁹ See sources cited *supra* note 78; see also MÉDECINS SANS FRONTIÈRES, 1998: *Big Pharma Versus Nelson Mandela* (MSF Access Campaign), <https://msfaccess.org/1998-big-pharma-versus-nelson-mandela>.

⁸⁰ See sources cited *supra* notes 77–79. The case is also known as "South Africa vs. the Drug Giants". Oxfam reports that shortly after South Africa enacted the 1997 amendments, the US government placed the country on its "Special 301" watch list and threatened trade sanctions unless the law was repealed, following intense lobbying by the Pharmaceutical Research and Manufacturers of America (PhRMA), a US trade association representing major drug companies such as GlaxoSmithKline and Bristol-Myers Squibb. OXFAM, *supra* note 77.

⁸¹ A compulsory licence is a legal mechanism for addressing issues arising from a patent. It allows a government authority, such as a ministry, court or statutory tribunal, to authorise someone other than the patent owner to manufacture the patented product, provided that the patent holder receives "adequate remuneration" in return.

⁸² J.H. Reichman & C. Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* 4, 20 (Int'l Ctr. for Trade & Sustainable Dev., 2003), <https://www.iprsonline.org/resources/docs/Reichman%20-%20Non-voluntary%20Licensing%20-%20Blue%205.pdf>.

⁸³ 't Hoen et al., *supra* note 69; see also Kit Oldham, *WTO Meeting and Protests in Seattle (1999)*, Part 1, HistoryLink.org (Oct. 13, 2009), <https://www.historylink.org/File/9183>.

⁸⁴ Nathan Ford, David Wilson, Gabriela Costa Chaves, Michel Lotrowska & Kannikar Kijtiwatchakul, *Sustaining Access to Antiretroviral Therapy in the Less-Developed World: Lessons from Brazil and Thailand*, 21 AIDS (Supp. 4) S21 (2007), <https://doi.org/10.1097/01.aids.0000279703.78685.a6>, <https://pubmed.ncbi.nlm.nih.gov/17620749/>.

in the 1990s to strengthen patent protection.⁸⁵ In response, Brazil amended its national law in 1996 to begin granting pharmaceutical patents, nine years ahead of the TRIPS deadline.⁸⁶

The HIV/AIDS issue began to attract more international political attention at the same time as the public health consequences of TRIPS became more widely recognised. In 2000, the Group of Eight (G8) countries also began to pay attention to health issues and to the pressing need to increase access to medicines.⁸⁷ Indian companies began offering medicines at a significantly lower cost than the originators' lowest price of roughly US\$1,000.⁸⁸ Notably, Cipla's offer was historic because it was open to everyone, in contrast to the originators, which gave case-by-case discounts only to specific countries.⁸⁹ This action by the Indian pharmaceutical industry exposed the monopolistic pricing of multinational companies during a public health emergency, demonstrated how generic competition can lower drug costs, and cemented India's position as the "pharmacy of the developing world".⁹⁰

On 14 November 2001, the Doha Declaration on the TRIPS Agreement and Public Health affirmed that all WTO Members, including LMICs, have the right to use TRIPS flexibilities to protect public health and to promote access to medicines for all.⁹¹ The Declaration affirms that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.⁹² This wording is somewhat softer than developing countries had proposed, but it still makes clear that protecting public health takes priority over protecting intellectual property rights. A crucial problem brought to light at Doha, however, remains unsolved.

According to Oxfam, a major issue left unresolved at Doha is the TRIPS Agreement's restriction on producing and exporting low-cost generic versions of new medicines.⁹³ These rules prevent countries lacking manufacturing capacity, which include the vast majority of LMICs, from accessing affordable treatments for diseases such as HIV/AIDS, malaria and tuberculosis.⁹⁴

⁸⁵ 't Hoen et al., *supra* note 69.

⁸⁶ *Id.*

⁸⁷ Johanna Hanefeld, *The Global Fund to Fight AIDS, Tuberculosis and Malaria: 10 Years On*, 14 CLINICAL MED. 54 (2014), <https://doi.org/10.7861/clinmedicine.14-1-54>, <https://pmc.ncbi.nlm.nih.gov/articles/PMC5873622/>.

⁸⁸ Donald G. McNeil Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, N.Y. TIMES, Feb. 7, 2001, <https://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html>.

⁸⁹ Carmen Pérez-Casas, Emilia Herranz & Nathan Ford, *Pricing of Drugs and Donations: Options for Sustainable Equity Pricing*, 6 TROPICAL MED. & INT'L HEALTH 960 (2001), <https://doi.org/10.1046/j.1365-3156.2001.00801.x>.

⁹⁰ Jagjit Kaur Plahe & Don McArthur, *After TRIPS: Can India Remain "the Pharmacy of the Developing World"?*, 44 S. ASIA: J. S. ASIAN STUD. 1167 (2021), <https://doi.org/10.1080/00856401.2021.1980839>.

⁹¹ Doha Declaration, *supra* note 42 (adopted Nov. 14, 2001).

⁹² *Id.* ¶ 4.

⁹³ OXFAM, *TRIPS and Public Health: The Next Battle*, *supra* note 22.

⁹⁴ See sources cited *supra* note 22.

Most LMICs lack the resources to produce generic medicines.⁹⁵ Nor can they afford expensive patented medicines; they therefore rely largely on outside suppliers, primarily India. India, however, presents an irony. Hailed as the “pharmacy of the world” as the world’s third-largest manufacturer of generic medicines (after China) and a major producer of vaccines, it faces a serious domestic problem: healthcare costs, of which the cost of medicines is a major part, push millions of its citizens into poverty every year.⁹⁶

It has been suggested that India should work with international alliances to push for reform of the product patent regime, so as to restore the process patent system, and should make greater use of compulsory licensing, which permits local production of patented drugs during public health crises. K.M. Gopakumar argues that although India has a thriving and dynamic domestic generic industry, which is necessary to use the TRIPS flexibilities, the country has faced institutional, legal and policy challenges in implementing those flexibilities since product patents were introduced by the 2005 amendment to the Patents Act, 1970 to comply with TRIPS.⁹⁷ He further states that pressure from pharmaceutical multinational corporations (MNCs), especially those based in the United States, limits India’s use of compulsory licensing, a situation that urgently needs to change.⁹⁸ Consequently, countries that rely heavily on Indian generics cannot effectively address access to medicines in pandemics.

Most developing countries cannot take advantage of compulsory licences to manufacture their own medicines because they lack production capacity.⁹⁹ Nor can they use such licences to import medicines, because Article 31(f) of the TRIPS Agreement restricts generic-producing countries from exporting to them.¹⁰⁰ Nearly all LMICs depend, to varying degrees, on imported medicines and are thus affected by the TRIPS restrictions on generic exports. A large proportion of the population of LMICs lives below the poverty line and bears most of the cost of medicines out of pocket. TRIPS restrictions on the production and export of affordable generics therefore have a significant impact on public health by raising the cost of medicines. In this sense, paragraph

⁹⁵ See sources cited *supra* note 22.

⁹⁶ Plahe & McArthur, *supra* note 90; see also Anant Phadke, *Why Medicines Are So Costly in India*, The Hindu Centre: The Arena (Dec. 9, 2024), <https://www.thehinducentre.com/the-arena/why-medicines-are-so-costly-in-india-html-version/article68950044.ece>.

⁹⁷ K.M. Gopakumar, *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime*, 3 L. & DEV. REV. 326 (2010), <https://doi.org/10.2202/1943-3867.1061>; see also K.M. Gopakumar, *TRIPS@30: Thirty Years of Widening Inequities in Access to Medicines*, THIRD WORLD RESURGENCE, no. 363, 2025, at 11–16, <https://twm.my/title2/resurgence/2025/363/cover01.htm>.

⁹⁸ Gopakumar, *Product Patents and Access to Medicines in India*, *supra* note 97.

⁹⁹ See sources cited *supra* notes 22, 30, 31 and 33; see also Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha “Solution”* (John M. Olin Program in Law & Econ., Working Paper No. 140, Univ. of Chi., 2002), <https://doi.org/10.2139/ssrn.300834>.

¹⁰⁰ TRIPS Agreement, *supra* note 23, art. 31(f).

6 of the Doha Declaration¹⁰¹ appears largely rhetorical and unworkable.¹⁰² Even with WIPO's technical assistance, LMICs have not taken full advantage of the transition period or other flexibilities.¹⁰³ For these reasons, there is a growing consensus among scholars that the benefits of intellectual property rights vary with a country's level of development, and that the one-size-fits-all approach of TRIPS is detrimental to LMICs.

In 2009, a report of the UK All Party Parliamentary Group on AIDS (APPG)¹⁰⁴ contended that when first-line HIV/AIDS medicines fail, switching to second-line treatment becomes a matter of survival.¹⁰⁵ The cheapest second-line treatment cost US\$590 per patient per year, about seven times more than the least expensive first-line drugs.¹⁰⁶ Where these medicines are patented by the originators and generics cannot be obtained, prices can rise to as much as seventeen times those of first-line treatments.¹⁰⁷ The report further noted that most second-line HIV/AIDS medicines are more complex than their first-line alternatives.¹⁰⁸ In the same year, WHO, the WTO and WIPO stepped up their trilateral cooperation.¹⁰⁹ That cooperation examines the flexibilities embedded in TRIPS that allow governments to develop policies suited to the specific circumstances of their nations and regions. Its practical implementation, however, has encountered numerous obstacles and constraints that have weakened fair and equitable access to medicines, and this is itself one of the main indications that the TRIPS flexibilities have failed.¹¹⁰

¹⁰¹ Doha Declaration, *supra* note 42, ¶ 6 (“We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”). The solution adopted was the General Council's decision of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003), later made permanent as Article 31bis. See GENERAL COUNCIL, *supra* note 39.

¹⁰² Vanessa B. Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?*, 3 GLOBALIZATION & HEALTH 3 (2007), <https://doi.org/10.1186/1744-8603-3-3>, <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-3>.

¹⁰³ Nirmalya Syam & Shirin Syed, *Impacts of LDC Graduation on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Cambodia, Djibouti, Senegal and Zambia* (U.N. Dep't of Econ. & Soc. Affs., Comm. for Dev. Pol'y Background Paper No. 57, June 15, 2023), <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/CDP-bp-2023-57.pdf>.

¹⁰⁴ ALL PARTY PARLIAMENTARY GROUP ON AIDS, *The Treatment Timebomb: Report of the Enquiry into Long-term Access to HIV Medicines in the Developing World* (July 2009), <https://www.appghivids.org.uk/projects>.

¹⁰⁵ *Id.* at 10.

¹⁰⁶ *Id.* at 12.

¹⁰⁷ *Id.*; see also MÉDECINS SANS FRONTIÈRES, *UTW: Interview with Campaign Pharmacist* (July 15, 2008), <https://msfaccess.org/utw-interview-campaign-pharmacist> (on the affordability, availability and adaptability of AIDS drugs in developing countries).

¹⁰⁸ ALL PARTY PARLIAMENTARY GROUP ON AIDS, *supra* note 104, at 12.

¹⁰⁹ *Trilateral Cooperation on Public Health, IP and Trade*, *supra* note 50.

¹¹⁰ The trilateral study of WHO, the WTO and WIPO on access to medical technologies and innovation acknowledges the role of TRIPS flexibilities in promoting access to medicines. Their practical implementation, however, has faced significant challenges and limitations that have undermined fair and equitable access to

On the basis of these facts and evidence, it may be concluded that the exclusive rights of pharmaceutical companies under the TRIPS patent system have been treated as untouchable and sacrosanct, with reliance placed only on flexibilities, on philanthropic initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria,¹¹¹ and on multidimensional, multi-institutional efforts such as the trilateral cooperation between WIPO, WHO and the WTO. This strategy has maintained the disparities in negotiating power between pharmaceutical companies and LMICs.

Apart from HIV/AIDS, COVID-19 was the other major pandemic to occur after the TRIPS Agreement took effect, nearly two decades after the Doha Declaration. A number of circumstances during the COVID-19 pandemic also revealed that the flexibilities available under TRIPS are insufficient to ensure fair and equitable access to essential medicines in pandemics.

B. COVID-19 pandemic and the failure of TRIPS flexibilities

The COVID-19 pandemic wrought havoc across the world, with some 779 million¹¹² reported cases and more than 7.1 million¹¹³ deaths. At the same time, millions of people lost their jobs.¹¹⁴ The World Bank projected in 2020 that the pandemic could push as many as 150 million people into extreme poverty by 2021, “extreme poverty” being defined as living on less than US\$1.90 a day.¹¹⁵ This shows the devastating socio-economic impact of the pandemic, which exacerbated

medicines, for many reasons: (a) procedural and political barriers to compulsory licensing; (b) the limitations of the paragraph 6 system (exporting medicines under compulsory licence); (c) patent barriers and evergreening practices; (d) inadequate use of TRIPS flexibilities owing to domestic constraints; (e) the impact of TRIPS-plus provisions and free trade agreements (FTAs); and (f) high costs and unequal distribution during pandemics. The “TRIPS flexibilities” related to access to medicines are therefore not sufficiently flexible. See sources cited *supra* notes 22, 30, 31 and 33.

¹¹¹ The Global Fund to Fight AIDS, Tuberculosis and Malaria is an international financing and partnership organisation created in 2002 to accelerate the fight against three of the world’s deadliest infectious diseases. Numerous other public funding mechanisms and philanthropic initiatives are dedicated to combating HIV/AIDS, such as PEPFAR (the U.S. President’s Emergency Plan for AIDS Relief), UNAIDS (the Joint United Nations Programme on HIV/AIDS), the World Bank’s HIV/AIDS programme, European Commission HIV/AIDS funding, the Bill & Melinda Gates Foundation, the Clinton Health Access Initiative (CHAI), the Elton John AIDS Foundation and the Wellcome Trust.

¹¹² WORLD HEALTH ORGANIZATION, *COVID-19 Cases*, *supra* note 4.

¹¹³ WORLD HEALTH ORGANIZATION, *COVID-19 Deaths*, *supra* note 5.

¹¹⁴ Marina A. Kartseva & Polina O. Kuznetsova, *The Economic Consequences of the Coronavirus Pandemic: Which Groups Will Suffer More in Terms of Loss of Employment and Income?*, 4 POPULATION & ECON. 26 (2020), <https://doi.org/10.3897/popecon.4.e53194>.

¹¹⁵ WORLD BANK, *COVID-19 to Add as Many as 150 Million Extreme Poor by 2021* (Press Release, Oct. 7, 2020), <https://www.worldbank.org/en/news/press-release/2020/10/07/covid-19-to-add-as-many-as-150-million-extreme-poor-by-2021>; see also Giovanni Valentini, *COVID-19 and Global Poverty: Are LDCs Being Left Behind?*, 32 EUR. J. DEV. RSCH. 1535 (2020), <https://doi.org/10.1057/s41287-020-00314-8>, <https://pmc.ncbi.nlm.nih.gov/articles/PMC7575865/>; see also Daniel Gerszon Mahler, Nishant Yonzan & Christoph Lakner, *The Impact of COVID-19 on Global Inequality and Poverty* (World Bank, Policy Research Working Paper No. 10198, 2022), <https://doi.org/10.1596/1813-9450-10198>, <https://documents1.worldbank.org/curated/en/099250510052241154/pdf/IDU01d94e70603dc804f990b6130751d75dccb52.pdf>.

global inequality and hardship.¹¹⁶ Several reports show that domestic violence increased during COVID-19, alongside a rise in substance abuse and mental health problems.¹¹⁷ In 2021, an estimated 250 million cases of malaria occurred globally, and about 620,000 people, many of them children, died of the disease.¹¹⁸ Other less severe but widespread health threats also cause a great deal of suffering. Trachoma, a preventable disease, has for instance left nearly 2 million people blind or visually impaired, severely affecting their ability to work and sustain their livelihoods.¹¹⁹ These figures emphasise the persistent burden of infectious diseases and their devastating consequences for individuals and communities.

After HIV/AIDS, the world once again confronted major health challenges during COVID-19, such as vaccine nationalism,¹²⁰ vaccine apartheid¹²¹ and vaccine hoarding,¹²² owing to deficiencies in the international patent bargain¹²³ system. Despite the various TRIPS flexibilities (such as Article 31bis, which implements paragraph 6 of the Doha Declaration), a voluntary pool of IP (the COVID-19 Technology Access Pool, C-TAP), public funding initiatives (such as COVAX) and multidimensional, multi-institutional efforts such as the trilateral cooperation of WIPO, WHO and the WTO to improve the supply of essential medicines during PHEICs, the COVID-19 pandemic exposed the persistent inequality in the TRIPS system, which has kept LMICs in a dependent position as importers of patented medicines.¹²⁴ Although the availability

¹¹⁶ Muhammad Fahad Sattar, Sehrish Khanum, Ahsan Nawaz, Muhammad Muzamal Ashfaq, Muhammad Anas Khan, Muhammad Jawad & Waseem Ullah, *COVID-19 Global, Pandemic Impact on World Economy*, 11 TECHNIUM SOC. SCI. J. 165 (2020), <https://doi.org/10.47577/tssj.v11i1.1503>, <https://heinonline.org/HOL/LandingPage?handle=hein.journals/techsj11&div=19&id=&page=>.

¹¹⁷ Diana Nadine Moreira & Mariana Pinto da Costa, *The Impact of the Covid-19 Pandemic in the Precipitation of Intimate Partner Violence*, 71 INT'L J.L. & PSYCHIATRY 101606 (2020), <https://doi.org/10.1016/j.ijlp.2020.101606>, <https://www.sciencedirect.com/science/article/pii/S0160252720300650>.

¹¹⁸ WORLD HEALTH ORGANIZATION, *World Malaria Report 2022* (2022), <https://www.who.int/publications/i/item/9789240064898>; see also Qiao Liu et al., *Millions of Excess Cases and Thousands of Excess Deaths of Malaria Occurred Globally in 2020 During the COVID-19 Pandemic*, 12 J. GLOB. HEALTH 05045 (2022), <https://doi.org/10.7189/jogh.12.05045>, <https://pmc.ncbi.nlm.nih.gov/articles/PMC9757497/>.

¹¹⁹ Seth Blumberg, Anna Borlase, Joaquin M. Prada, Anthony W. Solomon, Paul Emerson, Pamela J. Hooper, Michael S. Deiner, Benjamin Amoah, T. Déirdre Hollingsworth, Travis C. Porco & Thomas M. Lietman, *Implications of the COVID-19 Pandemic in Eliminating Trachoma as a Public Health Problem*, 115 TRANSACTIONS ROYAL SOC'Y TROPICAL MED. & HYGIENE 222 (2021), <https://doi.org/10.1093/trstmh/traa170>, <https://academic.oup.com/trstmh/article/115/3/222/6101238?login=false>.

¹²⁰ Caitlin R. Williams, Jocelyn Getgen Kestenbaum & Benjamin Mason Meier, *Populist Nationalism Threatens Health and Human Rights in the COVID-19 Response*, 110 AM. J. PUB. HEALTH 1766 (2020), <https://doi.org/10.2105/AJPH.2020.305952>.

¹²¹ Simar Singh Bajaj, Lwando Maki & Fatima Cody Stanford, *Vaccine Apartheid: Global Cooperation and Equity*, 399 LANCET 1452 (2022), [https://doi.org/10.1016/S0140-6736\(22\)00328-2](https://doi.org/10.1016/S0140-6736(22)00328-2), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)00328-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00328-2/fulltext).

¹²² *Covid Vaccine: WHO Warns of "Catastrophic Moral Failure"*, BBC NEWS (Jan. 18, 2021), <https://www.bbc.com/news/world-55709428>.

¹²³ Each patent granted is an exchange, or bargain, in which the inventor discloses a novel invention in return for a limited-term monopoly over its use. This is known as the patent bargain.

¹²⁴ Thambisetty et al., *supra* note 31.

of generic HIV/AIDS medicines has improved through active civil society engagement and NGO activism, the Doha Declaration has again failed to address the fundamental inequalities within the TRIPS framework that affect access to medicines globally.

As of February 2022, several reports indicated that developed countries such as the UK and several EU Member States had fully vaccinated 70–75% of their adult populations, whereas 85% of Africans had yet to receive a single dose.¹²⁵ Another report noted that as of October 2022 just 25% of people in low-income countries (LICs) had received at least one COVID-19 vaccine dose, compared with 72% in high-income countries.¹²⁶ While countries such as Israel, the US, the UK and Germany provided third and even fourth “booster” doses to their populations, billions of people in developing countries, including vulnerable healthcare workers, remained without a first dose.¹²⁷ Several reports show that while developing countries faced severe vaccine shortages, the US, the UK and the EU stockpiled the majority of doses, causing millions of vaccines to expire.¹²⁸ COVAX, an initiative co-led by WHO, Gavi and CEPI under the Access to COVID-19 Tools (ACT) Accelerator, was created to ensure equitable global access to COVID-19 vaccines through public–private cooperation.¹²⁹ The COVID-19 Vaccine Delivery Partnership was established in 2022 by WHO, UNICEF and Gavi to help countries with full vaccination coverage of 10% or lower.¹³⁰

Amid production shortages and unequal distribution, COVID-19 vaccine manufacturers declined offers of collaboration to boost production in the Global South, arguing that LMICs lacked the necessary manufacturing capacity.¹³¹ In 2021, production of the leading COVID-19 vaccines, mainly by Western companies such as Oxford–AstraZeneca, Pfizer–BioNTech, Moderna and Johnson & Johnson, remained limited, with few voluntary licensing deals to

¹²⁵ Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES (2023), <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>.

¹²⁶ Brenice Duroseau, Nodar Kipshidze & Rupali Jayant Limaye, *The Impact of Delayed Access to COVID-19 Vaccines in Low- and Lower-Middle-Income Countries*, 10 FRONTIERS PUB. HEALTH 1087138 (2023), <https://doi.org/10.3389/fpubh.2022.1087138>, <https://pmc.ncbi.nlm.nih.gov/articles/PMC9878283/>.

¹²⁷ AMNESTY INTERNATIONAL, *A Double Dose of Inequality: Pharma Companies and the Covid-19 Vaccines Crisis*, Index No. POL 40/4621/2021 (Sept. 22, 2021), <https://www.amnesty.org/en/documents/pol40/4621/2021/en/>.

¹²⁸ Melody Schreiber, *US Throws Out Millions of Doses of Covid Vaccine as World Goes Wanting*, GUARDIAN (Oct. 16, 2021), <https://www.theguardian.com/world/2021/oct/16/us-throws-out-millions-doses-covid-vaccine-world-shortages>.

¹²⁹ WORLD HEALTH ORGANIZATION, *COVAX: Working for Global Equitable Access to COVID-19 Vaccines*, <https://www.who.int/initiatives/act-accelerator/covax>.

¹³⁰ Omar Enzo Santangelo, Sandro Provenzano, Giuseppe Di Martino & Pietro Ferrara, *COVID-19 Vaccination and Public Health: Addressing Global, Regional, and Within-Country Inequalities*, 12 VACCINES 885 (2024), <https://doi.org/10.3390/vaccines12080885>, <https://pmc.ncbi.nlm.nih.gov/articles/PMC11360777/>.

¹³¹ Ashleigh Furlong, *Big Vaccine Makers Reject Offers to Help Produce More Jabs*, POLITICO (May 14, 2021), <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/>.

expand capacity.¹³² Partnerships such as J&J–Merck in the US,¹³³ AstraZeneca with the Serum Institute of India¹³⁴ and with Fiocruz in Brazil,¹³⁵ BioNTech’s joint venture with Fosun Pharma in China¹³⁶ and Pfizer–BioNTech’s agreement with Biovac in South Africa¹³⁷ helped, but were insufficient to meet global vaccine needs equitably. In Africa, vaccine production remained minimal; some doses were made locally, as under the J&J–Aspen deal, but most of them were exported to the EU rather than distributed within the continent.¹³⁸ Pfizer, BioNTech and Moderna were the primary beneficiaries of the system in 2021: Pfizer’s COVID-19 vaccine brought in some US\$36–37 billion in revenue,¹³⁹ BioNTech expected about €15.9 billion (some US\$18.6 billion) in vaccine revenue, roughly 0.5% of Germany’s GDP,¹⁴⁰ and Moderna projected US\$18.4 billion in vaccine sales.¹⁴¹ Press reports in early 2021 indicated that some LMICs had been quoted higher per-dose prices for the Oxford/AstraZeneca vaccine than some high-income countries.¹⁴²

South Africa argued at the TRIPS Council that, notwithstanding the desire of LMICs to produce their own vaccines, voluntary and charity-based programmes such as the COVID-19 Technology Access Pool (C-TAP) and COVAX had served mainly to preserve the existing patent system and the status quo.¹⁴³ According to WIPO data covering filings up to September

¹³² Thambisetty et al., *supra* note 31.

¹³³ *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines*, womenshealth.gov (blog).

¹³⁴ ASTRAZENECA, *Serum Institute of India Obtains Emergency Use Authorisation in India for AstraZeneca’s COVID-19 Vaccine* (press release, Jan. 6, 2021), <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>.

¹³⁵ MÉDECINS SANS FRONTIÈRES, *MSF Welcomes Fiocruz’s Step Towards Transparency of AstraZeneca Deal* (press release, Nov. 3, 2020), <https://msfaccess.org/msf-welcomes-fiocruz-step-towards-transparency-astrazeneca-deal>.

¹³⁶ Angus Liu, *BioNTech, Fosun Pharma Eye 1B Doses of COVID-19 Vaccine Capacity with New China JV*, FIERCE PHARMA (May 10, 2021), <https://www.fiercepharma.com/manufacturing/biontech-fosun-pharma-eye-1b-doses-covid-19-vaccine-capacity-new-china-jv>.

¹³⁷ PFIZER & BIONTECH, *Pfizer and BioNTech Announce Collaboration with Biovac to Manufacture and Distribute COVID-19 Vaccine Doses Within Africa* (press release, July 21, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac>.

¹³⁸ Gordon Brown, *The World Is Making Billions of Covid Vaccine Doses, So Why Is Africa Not Getting Them?*, GUARDIAN (Aug. 16, 2021), <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa-unprotected>.

¹³⁹ Julia Kollewe, *Pfizer Accused of Pandemic Profiteering as Profits Double*, GUARDIAN (Feb. 8, 2022), <https://www.theguardian.com/business/2022/feb/08/pfizer-covid-vaccine-pill-profits-sales>.

¹⁴⁰ *BioNTech Alone Could Lift German Economy by 0.5% This Year: Economist*, REUTERS (Aug. 10, 2021), <https://www.reuters.com/article/germany-economy-biontech-idUSL8N2PH32O/> (reporting BioNTech’s expected 2021 vaccine revenue of €15.9 billion, some US\$18.63 billion, as roughly 0.5% of German GDP).

¹⁴¹ Manojna Maddipatla & Manas Mishra, *Moderna Expects \$18.4 Billion in COVID-19 Vaccine Sales in 2021*, REUTERS (Feb. 25, 2021), <https://www.reuters.com/article/business/moderna-expects-184-billion-in-covid-19-vaccine-sales-in-2021-idUSKBN2AP1JF/>.

¹⁴² Carmen Paun & Ashleigh Furlong, *Poorer Countries Hit with Higher Price Tag for Oxford/AstraZeneca Vaccine*, POLITICO (Feb. 22, 2021), <https://www.politico.eu/article/astrazeneca-vaccine-cost-higher-in-poorer-countries-coronavirus/>.

¹⁴³ *23 February 2021: South Africa’s Interventions at the WTO TRIPS Council*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 1, 2021), <https://www.keionline.org/35453>.

2022, the leading countries in COVID-19 vaccine-related patent filings were China (573 applications), the United States (356), Germany (57), the Republic of Korea (56) and the Russian Federation (48).¹⁴⁴ Legal rights over COVID-19 vaccine technology were thus concentrated in a small number of countries and the companies based there.

Pharmaceutical firms in developed countries controlled the intellectual property (IP) in vaccines, and many experts argue that patents and trade secrets became chokepoints for global production. An essay in the *Harvard International Law Journal* concludes that while IP rights helped to finance vaccine development, “holding life-saving knowledge hostage in corporate monopolies to maximize private profit has tragic consequences” for access.¹⁴⁵ Cynthia Ho coins the term “IP nationalism” to describe how nations, primarily of the Global North, “are hoarding essential knowledge protected by intellectual property”.¹⁴⁶ She argues that this behaviour has contributed to “millions of unnecessary deaths” and that IP on pandemic treatments should instead be treated as a global public good to avoid another “vaccine apartheid”.¹⁴⁷ The corporate practice of controlling patents and trade secrets (IP hoarding) and the state-driven practice of “vaccine nationalism” (hoarding vaccine doses) thus expose the conflict and incoherence between existing legal and financial incentives and the goal of fair vaccine production, distribution and administration.

Meanwhile, to enhance global access to COVID-19 vaccines and health technologies, India and South Africa proposed a temporary waiver of certain intellectual property obligations under the TRIPS Agreement.¹⁴⁸ Sharp divisions between developed and developing countries, however, delayed consensus.¹⁴⁹ India and South Africa tabled the waiver proposal in October 2020,

¹⁴⁴ WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Exploring COVID-19 Vaccine Patents*, <https://www.wipo.int/en/web/patent-analytics/exploring-covid-19-vaccine-patents> (reporting patent filings through September 2022). Against this backdrop, Moderna sued Pfizer and its German partner BioNTech, alleging infringement of patents relating to their jointly developed Comirnaty vaccine. See MODERNA, *Moderna Sues Pfizer and BioNTech for Infringing Patents Central to Moderna’s Innovative mRNA Technology Platform* (Aug. 26, 2022), <https://news.modernatx.com/news/news-details/2022/Moderna-Sues-Pfizer-and-BioNTech-for-Infringing-Patents-Central-to-Modernas-Innovative-mRNA-Technology-Platform/default.aspx>.

¹⁴⁵ Madhavi Sunder & Haochen Sun, *Intellectual Property and “The Lost Year” of COVID-19 Deaths*, HARV. INT’L L.J. Online (Nov. 8, 2023), <https://journals.law.harvard.edu/ilj/2023/11/intellectual-property-and-the-lost-year-of-covid-19-deaths/>, also available at <https://scholarship.law.georgetown.edu/facpub/2565>.

¹⁴⁶ Cynthia M. Ho, *Confronting Intellectual Property Nationalism*, 100 DENV. L. REV. 109, 109 (2022), https://irp.cdn-website.com/8c66f319/files/uploaded/Vol.100_Issue1_CyHo_PRINT_4.pdf.

¹⁴⁷ *Id.* at 109–10.

¹⁴⁸ COUNCIL FOR TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa*, IP/C/W/669 (Oct. 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W/669.pdf&Open=True>; revised as IP/C/W/669/Rev.1 (May 25, 2021).

¹⁴⁹ Sarah Gabriele, *What Happened to the COVID-19 Vaccine Patent Waiver?*, BILL OF HEALTH (Petrie-Flom Ctr., Nov. 8, 2022), <https://petrieflom.law.harvard.edu/2022/11/08/what-happened-to-the-covid-19-vaccine-patent-waiver>. The negotiations ended in a narrower instrument, the Ministerial Decision on the TRIPS Agreement adopted at the Twelfth Ministerial Conference on 17 June 2022, which permits eligible developing country

arguing that the protection of private IP rights and profit-driven interests would distort priorities during the pandemic, favouring booster doses for high-income countries over initial vaccine access for LMICs. Most developing countries and many scholars around the world supported the waiver proposal and viewed it as an alternative to the “flexibilities” currently available under Articles 31 and 73 of the TRIPS Agreement.¹⁵⁰

Compulsory licensing under Article 31 of the TRIPS Agreement has several shortcomings.¹⁵¹ It operates on a product-by-product and country-by-country basis, which prevents a blanket compulsory licence for COVID-19 vaccines across all States. National procedures can be slow because of requirements beyond those in TRIPS, and many States hesitate to use compulsory licensing for fear of diplomatic backlash, trade sanctions or WTO disputes.¹⁵² Regulatory barriers such as data and marketing exclusivity further delay the approval of generic vaccines, since compulsory licences do not compel data sharing.¹⁵³ The “adequate remuneration” owed to right holders has also often led to disputes.¹⁵⁴ Article 31(f) of the TRIPS Agreement confines the use of compulsory licences mainly to domestic markets, while Article 31bis¹⁵⁵ permits export and import only under strict and complex conditions. Since the Doha Declaration, there has been only one completed use of the mechanism, Canada’s export of HIV medicines to Rwanda,¹⁵⁶ while Bolivia’s attempt in 2021¹⁵⁷ to obtain Johnson & Johnson vaccines from the

Members to authorise the use of patented subject matter required for the production and supply of COVID-19 vaccines. WORLD TRADE ORGANIZATION, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30, WT/L/1141 (June 22, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>. Paragraph 8 of the Decision required Members to decide within six months on its extension to COVID-19 diagnostics and therapeutics; no consensus was reached, and in February 2024 the Council for TRIPS reported that there was no consensus on an extension.

¹⁵⁰ Prabhash Ranjan & Praharsh Gour, *The TRIPS Waiver Decision at the World Trade Organization: Too Little Too Late!*, 13 ASIAN J. INT’L L. 10 (2023), <https://doi.org/10.1017/S2044251322000571>; see also PRITI PATNAIK, THE TRIPS WAIVER NEGOTIATIONS AT THE WORLD TRADE ORGANIZATION (OCTOBER 2020–JUNE 2022): A REPORTAGE FROM GENEVA HEALTH FILES (2022).

¹⁵¹ Aisling McMahon, *Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance*, 47 J. MED. ETHICS 142 (2021), <https://doi.org/10.1136/medethics-2020-106795>.

¹⁵² Ellen F.M. ’t Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V. Hogerzeil, *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL. WORLD HEALTH ORG. 185 (2018), <https://doi.org/10.2471/BLT.17.199364>.

¹⁵³ Ellen F.M. ’t Hoen, Pascale Boulet & Brook K. Baker, *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10 J. PHARM. POL’Y & PRAC. 19 (2017), <https://doi.org/10.1186/s40545-017-0107-9>.

¹⁵⁴ Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 010358 (2020), <https://doi.org/10.7189/jogh.10.010358>.

¹⁵⁵ GENERAL COUNCIL, *supra* note 39, https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

¹⁵⁶ Vincent, *supra* note 30; see also Holger P. Hestermeyer, *Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, 11 ASIL INSIGHTS, no. 28 (Dec. 10, 2007), <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and>.

¹⁵⁷ Benjamin Blanco, *With One Simple Decision, the Canadian Government Can Save Lives*, AL JAZEERA (Sept. 28, 2021), <https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives>.

Canadian manufacturer Biolyse stalled, which shows the limited efficacy of Article 31bis.¹⁵⁸ The experiences of HIV/AIDS and COVID-19 thus reveal that compulsory licensing is cumbersome, slow and unsuited to ensuring fair and equitable access to medicines during PHEICs such as pandemics.

Nor can the patent system be viewed in isolation. Another major issue is the extension of protection beyond the twenty-year patent term through the patent–trade secret duopoly.¹⁵⁹ Under IP law, easy-to-replicate inventions are typically patented to prevent copying, while hard-to-replicate inventions are often kept as trade secrets, which can provide protection well beyond the twenty-year patent term.¹⁶⁰ This dynamic also exposes three core flaws in the patent system:

1. **Inadequate disclosure:** patents often fail to meet their *quid pro quo* requirement of making information publicly available, known as disclosure.¹⁶¹ In practice, speculative filings based on limited or merely plausible details are common, while vital manufacturing processes are either omitted or fragmented across multiple applications.¹⁶²
2. **Delays in publication:** patent offices need publish applications only after eighteen months from filing, which leaves important information inaccessible during that period.¹⁶³ In reality the delays can be even longer, as follow-on patents are often filed later. More than two years into the pandemic, the actual number of patents in the COVID-19 vaccine field remained unclear.¹⁶⁴
3. **Strategic overlapping rights:** companies file multiple, slightly modified patents that build vast patent families around the same product.¹⁶⁵ This practice extends the duration and scope of monopolies, resulting in a de facto extension of protection well beyond twenty years.¹⁶⁶

The patent–trade secret duopoly therefore undermines the effective implementation of the flexibilities provided under the TRIPS Agreement. The experience of both the HIV/AIDS and COVID-19 pandemics demonstrates that these flexibilities have not ensured fair and equitable

¹⁵⁸ *Id.*

¹⁵⁹ Thambisetty et al., *supra* note 31, at 396.

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 397.

¹⁶² *Id.*

¹⁶³ *Id.* at 397–98.

¹⁶⁴ *Id.* at 397.

¹⁶⁵ *Id.* at 398.

¹⁶⁶ Olga Gurgula, *Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies: Two Different Concepts Sharing Similar Features*, 48 IIC 385 (2017), <https://doi.org/10.1007/s40319-017-0551-8>.

access to medicines, particularly for LMICs. The TRIPS waiver proposal advanced by developing countries represented a genuine effort to address this gap rather than a political manoeuvre. Its objective was to enable LMICs to manufacture vaccines and other essential health technologies to meet urgent public health needs, while strengthening domestic manufacturing capacity for future pandemic preparedness. These experiences indicate that reliance on TRIPS flexibilities alone is insufficient to guarantee fair and equitable access to medicines during PHEICs. Achieving equitable access requires policymakers and other stakeholders to move beyond the narrow debate centred on the patent system and its flexibilities.

IV. LEGAL MECHANISMS FOR ENSURING FAIR AND EQUITABLE ACCESS TO ESSENTIAL MEDICINES

This Part identifies the following legal mechanisms as essential to ensuring fair and equitable access to essential medicines in future pandemics.

A. Recalibrating WTO rules for fair and equitable access to essential medicines in pandemics

Srividhya Ragavan and Swaraj Paul Barooah emphasise that resolving global health challenges is fundamental to a stable and efficient international trading system.¹⁶⁷ The WTO should adapt its rules to respond better to future pandemics. The COVID-19 pandemic exposed serious weaknesses in global supply chains for medical products and showed that existing WTO rules were not designed to ensure the fair distribution of essential medicines, vaccines and other medical products during a global health emergency. As Mao-wei Lo observes, WTO rules have traditionally relied too heavily on exceptions and reactive measures rather than on preparing in advance for disruptions to global supply chains.¹⁶⁸

The WTO should work more closely with WHO, particularly in light of the WHO Pandemic Agreement adopted by the World Health Assembly in May 2025.¹⁶⁹ The Agreement provides a framework for pandemic preparedness, resilience, coordinated production, allocation of

¹⁶⁷ Srividhya Ragavan & Swaraj Paul Barooah, *Imagining Public Health as the Fulcrum of Global Trade*, in FRACTURES IN IP, TRADE, AND HEALTH: CENTERING A PUBLIC HEALTH FRAMEWORK 215 (2026), <https://doi.org/10.1093/9780197684085.003.0006>.

¹⁶⁸ Mao-wei Lo, *Recalibrating WTO Disciplines for Future Pandemics: Normative and Institutional Pathways for Ensuring Equitable Access to Medical Products*, J. WORLD INV. & TRADE 1 (2026) (advance article), <https://doi.org/10.1163/22119000-bja10111>.

¹⁶⁹ World Health Assembly Res. WHA78.1, WHO Pandemic Agreement (May 20, 2025). The Agreement is to open for signature only after the World Health Assembly adopts its annex on the Pathogen Access and Benefit-Sharing (PABS) system, which remained under negotiation in the Intergovernmental Working Group as of July 2026. See WORLD HEALTH ORGANIZATION, *WHO Member States Continue Negotiations on the Pathogen Access and Benefit Sharing Annex* (July 20, 2026), <https://www.who.int/news/item/20-07-2026-who-member-states-continue-negotiations-on-the-pathogen-access-and-benefit-sharing-annex>.

medical products and equitable access. WTO decision-makers and adjudicators should take relevant provisions of the Pandemic Agreement into account when interpreting WTO rules in disputes concerning trade measures affecting medical products. In this way, international trade law could become more supportive of global health objectives rather than treating public health concerns simply as exceptions to normal trade obligations.

B. Reforming TRIPS flexibilities through a pandemic amendment

The TRIPS Agreement itself requires amendment to address the deficiencies exposed during HIV/AIDS and COVID-19. Despite the Doha Declaration and the paragraph 6 system, the core structural problems remain: the domestic-market restriction in Article 31(f) (only partially addressed by Article 31bis), the ambiguous “adequate remuneration” standard, the absence of a blanket authorisation for pandemic response, and the lack of any mechanism to override trade secrets or data exclusivity.

A “pandemic amendment” to TRIPS should include: (a) an automatic, non-waivable compulsory licensing mechanism¹⁷⁰ triggered by the declaration of a PHEIC or pandemic emergency, without the need for product-by-product authorisation; (b) a fixed, low royalty rate for pandemic-related products, determined by an independent body; (c) the elimination of data exclusivity and market protection periods during pandemics; (d) a clear provision that trade secrets cannot be invoked to block generic production during health emergencies; and (e) an expedited dispute resolution mechanism for access-to-medicines cases, reversing the burden of proof so that patent holders must justify why a compulsory licence should not be granted.

C. Establishing a legally binding technology transfer framework

The voluntary, “mutually agreed terms” approach to technology transfer proved inadequate during both the HIV/AIDS and COVID-19 pandemics. As Nithin Ramakrishnan and K.M. Gopakumar observed of the revised negotiating text of March 2024, the technology transfer provisions of the proposed pandemic instrument were non-binding, delayed and narrowly framed.¹⁷¹ A legally binding technology transfer framework should therefore move beyond voluntary commitments and establish clear, enforceable obligations on States, technology holders and relevant institutions to ensure that critical pandemic-related technologies, know-

¹⁷⁰ An automatic, non-waivable compulsory licensing mechanism is a legal framework under which a government automatically grants permission to third parties (or to itself) to use a patented invention without the patent owner’s consent, and the owner cannot opt out of or waive the requirement. On compulsory licensing generally, see WORLD TRADE ORGANIZATION, *TRIPS and Health: Frequently Asked Questions: Compulsory Licensing of Pharmaceuticals and TRIPS*, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

¹⁷¹ Nithin Ramakrishnan & K.M. Gopakumar, *WHO: Revised Pandemic Instrument Text Onerous, Inequitable for Developing Countries*, TWN Info Service on Health Issues (Mar24/06) (Third World Network, Mar. 11, 2024), <https://twn.my/title2/health.info/2024/hi240306.htm>.

how and manufacturing capabilities are transferred rapidly and equitably to countries and regions that lack sufficient production capacity.

Such a framework should include: (a) binding obligations for the timely transfer of relevant technologies, technical information, manufacturing know-how and other forms of technological assistance necessary for the development and production of pandemic-related products; (b) mandatory disclosure and sharing of manufacturing processes, technical specifications, quality-control information and other necessary know-how during declared public health emergencies, subject to appropriate safeguards and fair compensation where warranted; (c) contractual and institutional mechanisms requiring technology holders that benefit from public funding, public procurement or other forms of public support to undertake meaningful technology-transfer commitments; and (d) the establishment and expansion of regional manufacturing and technology-transfer hubs in LMICs, supported by sustained technical assistance, training, regulatory cooperation, workforce development and access to the underlying technological capabilities required for independent and sustainable production.

D. A human rights-based approach for pandemic preparedness and response

The HIV/AIDS and COVID-19 pandemics were not only public health crises but also major human rights crises. In the wake of COVID-19, scholars have assessed the pandemic through the principles of the right to health, non-discrimination, freedom of expression, social and economic rights and international cooperation.¹⁷² They argue that governments failed in several ways: some suppressed information and criticism, some disregarded scientific evidence, and many imposed restrictions without adequately protecting affected populations.¹⁷³ At the same time, years of underinvestment in health systems and social protection left poorer and marginalised communities particularly vulnerable, especially in LMICs.¹⁷⁴ In this sense, the pandemic exposed a fundamental tension: governments have a duty to protect public health, but the measures used to do so must also respect human rights and be scientifically justified, proportionate and as minimally restrictive as possible.

E. Strengthening the WHO's normative and enforcement authority

The WHO's ability to ensure equitable access is currently constrained by its distorted financing model, its dependence on voluntary contributions and its lack of enforcement authority. As

¹⁷² Lawrence O. Gostin, Eric A. Friedman, Sara Hossain, Joia Mukherjee, Saman Zia-Zarifi, Chelsea Clinton, Umunyana Rugege, Paulo Buss, Miriam Were & Ames Dhai, *Human Rights and the COVID-19 Pandemic: A Retrospective and Prospective Analysis*, 401 LANCET 154 (2023), [https://doi.org/10.1016/S0140-6736\(22\)01278-8](https://doi.org/10.1016/S0140-6736(22)01278-8), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01278-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01278-8/fulltext).

¹⁷³ *Id.*

¹⁷⁴ *Id.*

Charles Clift observes, the WHO relies largely on moral authority and technical guidance; it cannot compel States or private actors to adopt equitable policies.¹⁷⁵ Although the WHO Constitution empowers the World Health Assembly to adopt binding international agreements, Kevin Klock noted in 2013 that it had used this power only three times.¹⁷⁶ Critics argue that this underuse harms the WHO's legitimacy. As Lawrence O. Gostin and Allyn L. Taylor have long argued, global health law requires not only norms but also the institutional capacity to implement and enforce them.¹⁷⁷ Without such capacity, even the strongest normative commitments remain aspirational. WHO bodies such as the World Health Assembly (WHA) and the Intergovernmental Working Group (IGWG) should therefore develop legally binding instruments to ensure fair and equitable access to essential medicines in pandemics.

F. Decolonizing global health law through regionalization and South-South cooperation

One important pathway towards decolonizing the global health regime (GHR) is the strengthening of regional health governance and South-South cooperation. The concentration of normative and institutional authority within global health institutions has often resulted in health priorities and responses being shaped predominantly by actors from the Global North.¹⁷⁸ Regionalization offers an alternative institutional structure through which States in the Global South can develop collective approaches to health emergencies that are more responsive to their regional circumstances and priorities. As Omowamiwa Kolawole and Uchechukwu Ngwaba argue, the Africa Centres for Disease Control and Prevention (Africa CDC) provides an important example of regionally driven health governance and an emerging form of decolonization.¹⁷⁹

V. CONCLUSION

The experiences of HIV/AIDS and COVID-19 reveal that TRIPS flexibilities, although important in principle, remain inadequate in practice because of structural limitations, political pressures, intellectual property interests and unequal bargaining power between developed and

¹⁷⁵ CHARLES CLIFT, THE ROLE OF THE WORLD HEALTH ORGANIZATION IN THE INTERNATIONAL SYSTEM (Chatham House, Centre on Global Health Security, 2013), <https://www.chathamhouse.org/sites/default/files/publications/research/2013-02-01-role-world-health-organization-international-system-clift.pdf>.

¹⁷⁶ Kevin A. Klock, Note, *The Soft Law Alternative to the WHO's Treaty Powers*, 44 GEO. J. INT'L L. 821 (2013), <https://ssrn.com/abstract=3931956>.

¹⁷⁷ Lawrence O. Gostin & Allyn L. Taylor, *Global Health Law: A Definition and Grand Challenges*, 1 PUB. HEALTH ETHICS 53 (2008), <https://doi.org/10.1093/phe/phn005>.

¹⁷⁸ Matiangai Sirleaf, *Introduction to the Symposia on Global Health at a Crossroads*, 120 AJIL UNBOUND 40 (2026), <https://doi.org/10.1017/aju.2026.10062>.

¹⁷⁹ Omowamiwa Kolawole & Uchechukwu Ngwaba, *Decolonizing Global Health Law through Regional Health Governance: Africa Centre for Disease Control as an Early Example*, 120 AJIL UNBOUND 80 (2026), <https://doi.org/10.1017/aju.2025.10050>.

developing countries. The analysis therefore proposes a shift from fragmented and largely voluntary mechanisms towards binding, enforceable and equity-centred legal arrangements, including recalibrated WTO rules, a pandemic-specific amendment to TRIPS, mandatory technology transfer, greater normative and enforcement authority for the WHO, stronger regional and South-South cooperation, and a unified World Health System (WHS).

From a TWAIL perspective, however, legal reform alone cannot overcome the entrenched power asymmetries within the global health regime; sustained political mobilisation, civil society advocacy, collective action by developing countries and the redistribution of decision-making authority are essential to make these reforms effective. Ultimately, the legitimacy of the international pandemic response will depend not merely on its capacity to detect and contain future outbreaks, but on its ability to ensure that the benefits of scientific innovation and essential medical technologies are shared fairly and equitably. The challenge, therefore, is to transform equity and solidarity from aspirational principles into binding legal obligations supported by effective enforcement, financing, institutional accountability and meaningful participation, thereby creating a world health system capable of preventing the inequities witnessed during HIV/AIDS and COVID-19 from being repeated in future pandemics.
