The Summit of the Future: Health Technologies for the Common Good

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Abstract

Even decades after the emergence of health technologies for prevention and treatment of diseases, those same diseases continue to shatter lives around the developing world, among the world's poorest. This policy brief will present two detailed illustrative case studies. First, in the space of HIV/AIDS innovations, people living in poorer countries have gained access to cutting-edge diagnostics and treatments well after their wealthier counterparts. The second case study will examine the recent scientific advance in mRNA vaccines, developed for COVID-19. With their tremendous potential to shorten future pandemics, it is important to resolve the production, distribution, and access issues around mRNA technology without delay.

At the High-Level Meeting on Pandemic Prevention, Preparedness and Response, held in September 2023, the international community committed to make access to pandemic-related products, including vaccines, diagnostics and therapeutics, timely, sustainable and equitable (Declaration). The Summit of the Future, to be held in September 2024, provides an opportunity to follow up on this commitment. Via two illustrative case studies, this policy brief questions the existing system for development and uptake of health technologies and breakthroughs. The first case study discusses HIV/AIDS treatments where, even decades after their emergence, and despite tremendous medical progress, there is a shocking disparity in access across the globe. The second case study will examine the more recent scientific advance in mRNA vaccines, developed for COVID-19. With tremendous potential to be used in the event of other pandemics, it is important to get the production, distribution and access issues around mRNA technology resolved, without delay. This brief makes some bold recommendations for consideration by world leaders.

Innovation is inherently cumulative and collective in nature and entails many risks ranging from technological risks, market risks and a whole range of uncertainties. Private actors in many cases do not have the means to take on these risks and governments step in to enable this innovation and provide vital long-term finance (Mazzucato 2018). But it is important to ensure that early-stage public support promotes the public good and not just excess profits for a few.

Intellectual property rights (IPR), including patents, copyrights and trademarks, grant monopoly rights to an inventor. Given a range of actions from companies that amount to taking undue advantage of the IPR regime, the existing regime is misused resulting in higher prices, less innovation and inefficient expenditure including on lawsuits (Cheng and Parra-Lancourt 2020 and Bostrom and Nayyar 2023). Such actions include spurious lawsuits to delay or discourage competitors (Torrisi et al. 2016), creating patent "thickets" that are difficult to navigate (Hall, Helmers, and von Graevenitz 2015), and patenting technologies developed with public money (Flaherty 2019; Mueller 2023). Private companies in the West that hold the property rights over the latest medical technologies, often built on the shoulders of public research and public funds, milk them for profits in the billions, for years. Meanwhile, globally, access to the latest advances is absent and large pockets of deprivation remain. How the benefits from these innovations are distributed is far from fair and creates patterns of injustice and human tragedy.

HIV/AIDS - Disparities at Every Step

A well-known example of unequal global access to lifesaving medical technologies is the AIDS epidemic. In the space of HIV/AIDS innovations, as in other areas of medicine, people living in poorer countries systematically gain access to cutting-edge medical innovations after their wealthier counterparts. Even then, these technologies remain out of reach for many due to high prices and institutional barriers. Such inequity is clearly visible in historical data on access to antiretroviral therapies (ART), the breakthrough technology that revolutionized AIDS treatment. It is clear from Fig. 1 that wealthy countries had vastly more access to ART more quickly than their poorer counterparts.

Figure 1. ART Coverage by Region over Time

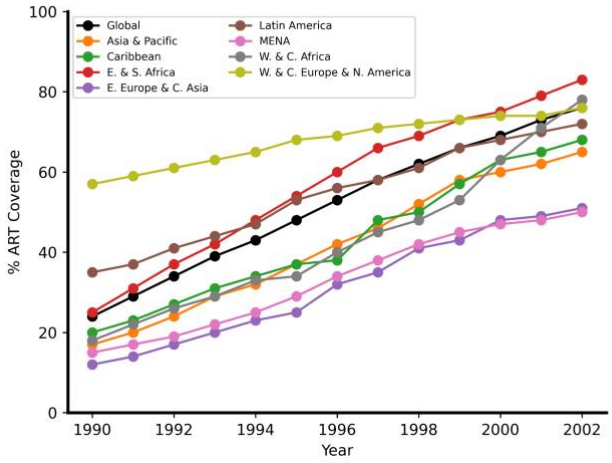

Fig 1. ART coverage as a percent of total HIV cases by region, 1990-2002 (the years for which data is available). Data source: UNAIDS.

Evidently, it took more than a decade since the first ART was approved for use in the United States (in 1987) for any region to catch up to Western & Central Europe and North America. This becomes especially egregious when one considers the prevalence rates around the world. The prevalence rates in Eastern and Southern Africa (ESA) far outstrip the rest of the world (UNAIDS). Though international assistance gradually boosted ART coverage in the region, it still lagged the world's wealthiest countries for years. By prevalence alone, ESA most needed rapid access to ART. How many lives could have been saved if this lifesaving intervention had been distributed more equitably?

Firms' fierce protectiveness of their intellectual property, often supported by their (wealthy) governments, was one barrier to early and widespread access to ART. IPR was one factor that inhibited global production of the drugs, especially the production of affordable generic versions. South Africa, under President Nelson Mandela, led the charge from the global South to challenge these barriers, including by allowing the production of generics despite international resistance to the practice (George 2011).

Remedies do now exist in the international framework governing intellectual property, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in large part thanks to South Africa's efforts. So-called "TRIPS flexibilities", however, rarely work in practice. For example, Brazil and Thailand both saw success in expanding access to ART using compulsory licensing, which allows governments to issue licenses without the patent holder's consent (Cottingham & Berer 2011). However, this was only achieved with the investment of substantial financial and human resources from both the government and nongovernmental organizations. Even so, both governments have continued to face pressure from the US and other powerful economic actors to limit compulsory licensing (Rosenberg 2014).

Even where affordable medical technologies are made available, many countries lack the infrastructure and institutions necessary to ensure timely, consistent delivery to all who need it. This has been a factor in delaying the entry of HIV testing in Africa, for example. Despite their potential for reaching remote populations in high-transmission regions (Ekouevi et al. 2020), the first HIV self-test (HIVST) kits did not reach Africa until 2015, a full three years after they reached American markets (Ingold et al. 2019). Even then, underdeveloped and inconsistent regulatory environments and weak healthcare systems limited access to reliable, affordable, and convenient test kits (ibid.). New drugs and technologies are generally not developed with poor country contexts in mind, which means that separate feasibility tests in these under-resourced areas must be conducted before distribution can begin. Such was the case for HIVST throughout sub-Saharan Africa (Ingold et al. 2019; Ekouevi et al. 2020).

These examples underscore the importance of strengthening health systems and regulatory environments to facilitate the distribution of health technologies. The current charity model, based on ad-hoc donations of money or medications, leaves countries and patients dependent on an uncertain resource stream. Indeed, even as donor funding for AIDS treatment recedes, prices for both originator and generic drugs are expected to double or triple between 2016 and 2026 (Beck et al. 2019). We cannot afford to continue such a system for future diseases. The AIDS epidemic has demonstrated quite clearly that, in a health context, delays can lead to preventable deaths. Sadly, the recent COVID-19 pandemic highlighted that the international community has not applied these lessons.

mRNA Vaccines –Maximizing the Potential beyond COVID-19

The mRNA technology, built on collective research, public funding and incentives, is a perfect example of risks being in the public-private domain, but rewards, including through the patents system, being privatized (Mazzucato 2023a). Moderna received nearly $10 billion (US) in taxpayer funding to develop the mRNA-based COVID vaccine and provide doses to the government. The central component of the vaccine is a genetic sequencing innovation resulting from ongoing collaboration between the US National Institute of Health and Moderna (Stolberg and Robbins 2021). After

the successful launch of the vaccine, in its filing for a US patent, Moderna only listed its own employees.

Severe damage was caused by global vaccine inequity during the COVID-19 pandemic. Some estimates find that there were more than 1 million excess deaths in the global South (Moore et al 2022). mRNA technology should not be under the exclusive control of a few private companies. It is being tested for use against other diseases and is likely to be a very important tool in the arsenal against future pandemics and health crises (Wang, YS., Kumari, M., Chen, GH. et al 2023).

However, this will depend on the international community getting it right on the governance of these technologies. Developing countries face many barriers in accessing frontier technologies and the IPR system, with international trade agreements in a supporting role, inhibits their access and the free flow of technical knowhow. Both Oxford-AstraZeneca and Pfizer-BioNTech received public funding and large advance purchase commitments that helped them bring their COVID vaccines to market. In the case of Oxford-AstraZeneca, public funding was conditioned on the company setting lower prices. Pfizer-BioNTech was free to set higher prices. It also rebuffed calls to offer licensing arrangements and technology transfers (Mazzucato 2023b).

Even today, the rates of vaccination remain lower in poorer countries, which also have disproportionately high vaccination costs. The poorest 27 countries comprise 8.6 percent of the global population but account for only 1.3 percent of all vaccines administered as of June 2022 (UNDP COVID-19 Vaccine Equity Dashboard). Fig. 2 demonstrates this global disparity in vaccination rates, and the disproportionate cost borne by poorer countries trying to vaccinate their populations.

Moderna's listing of only its own employees on the patent filing was an attempt to have exclusive say on which countries get to manufacture and access its COVID vaccine. As the sole patent holder, it would exert full control over global production and distribution. For now, Moderna has backed down and not completed the process of the issuance of the patent. At the height of the COVID pandemic, activists advocated the US government to use its role as co-inventor of the Moderna vaccine to extend international licenses for wider manufacturing and supply of the vaccine in the developing world (Rowland 2021). How the case of Moderna is resolved will have implications for future global distribution of health technologies.

Figure 2. Vaccination Rates by Cost, Disaggregated by HDI

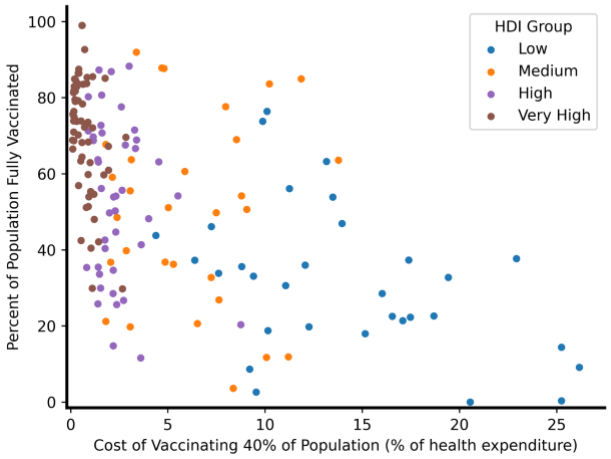

Fig 2. The percentage of the total population that has been fully vaccinated, as a function of the cost of vaccinating 40% of the population. The vaccination cost is expressed as a percentage of the country's total expenditure on healthcare. Marker color indicates the country's grouping in the Human Development Index (HDI): low (<0.550), medium (0.550 - 0.699), high (0.700 - 0.799), or very high (0.800 - 1.0). Data source: UNDP COVID-19 Vaccine Equity Dashboard.

Developing country governments and pharma companies have to navigate a complex and murky intellectual property landscape, running the risk of running afoul of trade agreements and being penalized. The WHO has established its mRNA vaccine technology hub in Cape Town centered around the South African firm Afrigen Biologics' reverse engineering of the Moderna vaccine to develop its own vaccine which has shown early promise (Dutton 2022). The hub pursued its own vaccine after global firms, including Moderna and Pfizer, declined to transfer the intellectual property to replicate the vaccines. The hub will manufacture mRNA vaccines and train scientific groups known as spokes, currently from five other countries: Egypt, Kenya, Nigeria, Senegal and Tunisia. While Moderna has indicated that it will not enforce its patents in South Africa against the mRNA hub for any COVID-19 related products, there is no such pledge for vaccines that the mRNA hub may develop to treat other diseases including tuberculosis, HIV, and cancer (Kana et al 2023).

Member States of the World Health Organization (WHO) have agreed to a global process to negotiate and draft a convention, agreement or other international instrument under the Constitution of the WHO to strengthen pandemic prevention, preparedness and response. As the Pandemic Prevention, Preparedness

and Response Accord makes progress, the question of mRNA technologies must be addressed. We must not repeat the mistakes from the AIDS pandemic.

Policy recommendations / conclusions

As part of stronger governance of innovation, here are some main policy levers that should be used:

1. Global public goods - Multistakeholder agreements to designate some technologies as global public goods, with full access to intellectual property, have been proposed (Bostrom and Nayyar 2023). The case of making mRNA technologies global public goods, with developing countries free to access and adopt these technologies, is very strong. An mRNA technology transfer program, launched by the WHO with a hub in South Africa, is one effort to realize this objective.

2. Fair distribution of rewards and risk – Having provided the backing for fundamental research, governments must ensure that the benefits from successful applications are accessible for the greater good. There are conditions that can be attached to public support that ensure that not just the risks of supporting innovation are shared but also the rewards (Whitfill and Mazzucato 2023). These could include requirements that profits be reinvested back in production rather than used for stock buybacks or executive pay, public agencies retaining equity or royalties of successful ventures, capping prices of publicly funded medicines, and other measures.

3. Patents reform – The patents regime does not optimize the flow of technology and know-how for the attainment of the Sustainable Development Goals (SDGs) and is in need of updating (Baker, Jayadev, & Stiglitz 2017; Bostrom & Nayyar 2023). International bodies such as the WTO should take proactive measures to shield developing countries from retaliatory measures by more powerful actors against the use of TRIPS flexibilities to ensure access to public health technologies.

4. Systems-level investment - Instead of precarious charity arrangements, including drug donations and bilateral aid, international public health efforts should help countries and regions invest in their public health systems. Public money is needed to strengthen infrastructure and regulatory environments, train staff, and jumpstart domestic innovation (Global Sustainable Development Report 2023). These more forward-looking investments by bilateral and international donors can prevent the next pandemic from exhibiting the same inequalities as HIV/AIDS and COVID-19.

References

Baker D, Jayadev A, Stiglitz J. Innovation, intellectual property, and development: A better set of approaches for the 21st century. CEPR (Washington, DC); 2017 [cited 2024 Mar 09]. Available from: https://cepr.net/report/innovation-intellectual-property-and-development-a-better-set-of-approaches-for-the-21st-century/.

Beck EJ, Mandalia S, DongmoNguimfack B, Pinheiro E, 't Hoen E, Boulet P, Stover J, Gupta A, Juneja S, Habiyambere V, Ghys P, Nunez C. Does the political will exist to bring quality-assured and affordable drugs to low- and middle-income countries? Global Health Action, 2019; 12.

Bostrom A, Nayyar S. Fit for purpose? The patents regime, the Fourth Industrial Revolution, and sustainable development. Data & Policy, 2023; 5(18).

Cheng HWJ, Parra-Lancourt M. The Fourth Industrial Revolution, Development and Intellectual Property - the World Economic and Social Survey 2018 and Beyond. In: Heath C, Sanders AK, Moerland A, editors. Intellectual Property Law and the Fourth Industrial Revolution. Wolters Kluwer; 2020.

Cottingham J, Berer, M. Access to essential medicines for sexual and reproductive health care: the role of the pharmaceutical industry and international regulation. RHM, 2011; 19(38); 69-84.

Dutton J. First African-made mRNA vaccine, a test platform for the future. Nature Africa, 2022 Oct 26 [cited 2024 Mar 09]. Available from: https://www.nature.com/articles/d44148-022-00151-3.

Ekouevi DK, Bitty-Anderson AM, Gbeasor-Komlanvi FA, Coffie AP, Eholie SP. HIV self-testing: The key to unlock the first 90 in West and Central Africa. IJID, 2020; 95; 162-166.

Flaherty B. Federally funded research drives nearly one-third of U.S. patents, report finds. STAT News, 2019 [cited 2024 Apr 28]. Available from: https://www.statnews.com/2019/06/20/federal-finding-research-patents/.

George E, The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines. Ind. J. Glo. Leg. Stu., 2011; 18(1); 167-197.

Hall BH, Helmers C, von Graevenitz G. Technology Entry in the Presence of Patent Thickets. National Bureau of Economic Research Working Paper 21455, 2015. Available from: https://doi.org/10.3386/w21455.

Independent Group of Scientists appointed by the Secretary-General. Global Sustainable Development Report 2023: Times of crisis, times of change: Science for accelerating transformations to sustainable development. United Nations (New York); 2023.

Ingold H, Mwerinde O, Ross AL, Leach R, Corbett EL, Hatzold K, Johnson CC, Ncube G, Nyirenda R, Baggaley RC. The Self-Testing AfRica (STAR) Initiative: accelerating global access and scale-up of HIV self-testing. J. Intl. AIDS Soc., 2019; 22(S1). Available from: https://onlinelibrary.wiley.com/doi/10.1002/jia2.25249.

Kana BD, Arbuthnot P, Botwe BK, Choonara YE, Hassan F, Louzir H, Matzos P, Moore PL, Muhairwe A, Naidoo K, Ndomondo-Sigonda M, Madhi SA. Opportunities and challenges of leveraging COVID-19 vaccine innovation and technologies for developing sustainable vaccine manufacturing capabilities in Africa. The Lancet, 2023; 23(8); E288-E300.

Mazzucato M. The Value of Everything: Making and Taking in the Global Economy. Penguin Random House; 2018.

Mazzucato M, Governing the economics of the common good: from correcting market failures to shaping collective goals. J. Economic Policy Ref., 2023a; 21(7); 1-23.

Mazzucato M. Unlocking Health Technology's Potential for All. Project Syndicate, 2023b Oct 24 [cited 2024 Mar 09]. Available from: https://www.project-syndicate.org/commentary/health-technology-mrna-governance-conditions-to-serve-common-good-by-mariana-mazzucato-2023-10.

Moore S, Hill EM, Dyson L, Tildesley MJ, Keeling MJ. Retrospectively modeling the effects of increased global vaccine sharing on the COVID-19 pandemic. Nature Medicine, 2022; 28; 2416-2423.

Mueller B. After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique. The New York Times, 2023 February 23 [cited 2024 Apr 28]. Available from: https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html.

Rosenberg ST. Asserting The Primacy of Health Over Patent Rights: A Comparative Study of the Processes that Led to the Use of Compulsory Licensing in Thailand and Brazil. Dev. World Bioethics, 2014; 14(2); 83-91.

Rowland C. Advocates want NIH to use its Moderna vaccine patent to push for global access. Washington Post, 2021 Mar 25 [cited 2024 Mar 09]. Available from: https://www.washingtonpost.com/business/2021/03/25/moderna-vaccine-patent-nih/.

Stolberg SG, Robbins R. Moderna and U.S. at Odds Over Vaccine Patent Rights. New York Times, 2021 Nov 9 [cited 2024 Mar 09]. Available from: https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.

Torrisi S, Gambardella A, Giuri P, Harhoff D, Hoisl K, Mariani M. Used, blocking and sleeping patents: Empirical evidence from a large-scale inventor survey. Research Policy, 2016; 45(7); 1374-1385.

UNAIDS. AIDSinfo: Global Data on HIV Epidemiology and Response. Available from: https://aidsinfo.unaids.org/.

UNDESA. Global Sustainable Development Report (GSDR) 2023. Available from: https://sdgs.un.org/gsdr/gsdr2023.

UNDP. COVID-19 Vaccine Equity Dashboard. Available from: https://data.undp.org/insights/vaccine-equity.

UN General Assembly. Political Declaration of the United Nations General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response (Zero Draft). United Nations (New York); 2023 Sep 20.

Wang Y-S, Kumari M, Chen G-H, Hong M-S, Yuan JP-Y, Tsai J-L, Wu H-C. mRNA-based vaccines and therapeutics: an in-depth survey of current and upcoming clinical applications. J. Biomed. Sci., 2023; 30(84).

Whitfill T, Mazzucato M. ARPA-H Could Offer Taxpayers a Fairer Shake. Iss. Sci. Tech., 2023; 39(4); 51-53.

World Health Organization (WHO). Pandemic prevention, preparedness and response accord (Q&A). WHO; 2023 Jun 28 [cited 2024 Mar 09]. Available from: https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord.