Governance of Public Health Innovation in the Shadow of COVID-19

Chidi Oguamanam

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Contents

Author

Dr. Chidi Oguamanam
coguaman@uottawa.ca
Oguamanam is a Professor in the Faculty of Law at the University of Ottawa (uOttawa) and holds the uOttawa Research Chair in Sustainable Bio-innovation, Indigenous Knowledge Systems and Global Knowledge Governance. Oguamanam is also affiliated to uOttawa's Centre for Law, Technology and Society, Centre for Health Law, Policy and Ethics, and Centre for Environmental Law and Global Sustainability. He is an Adjunct Professor at the School of Law, University of Venda, South Africa, and was a Senior Fellow at the Centre for International Governance Innovation (CIGI) in Waterloo, Canada. Oguamanam is an Open AIR co-founder and co-lead, and guides Open AIR's research on African innovation grounded in Indigenous knowledge systems. He is a Fellow of the African Academy of Sciences (AAS) and has been inducted into the Royal Society of Canada's College of New Scholars, Artists and Scientists.

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Abstract

This Open AIR Working Paper 28 explores innovations in the delivery of universal care to achieve UN Sustainable Development Goal (SDG) 3: "Ensure healthy lives and promote well-being for all at all ages". In this exploration, issues related to governance and ownership of global vs. local innovation, including but not limited to the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), are considered. In addition, this paper covers the roles of intellectual property (IP), licensing, and regulatory bodies in shaping access to, and influencing distribution of, health benefits and outcomes. A core insight presented in this paper is that successfully achieving the goals of health and well-being is inseparable from other dimensions of sustainable development—particularly climate action but also access to clean water, to education, and to social welfare support. This paper also points to the fact that the lessons of the COVID-19 pandemic are not about vaccines only. The lessons are also about ancillary medical innovations. Future pandemics are anticipated to each have their own unique character, thus requiring response agility and adaptation—both technological and regulatory—beyond medicines and therapeutics. Moreover, data will drive future pandemic and public health responses, making appropriate data governance and regulation a priority issue.

Keywords

COVID-19, global public health, pandemic, Sustainable Development Goal (SDG) 3, TRIPS Agreement, intellectual property (IP), regulation, low- and middle-income countries (LMICs)

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I. Introduction

One of the direct and most disturbing outcomes of current climate change is the anticipated increased frequency of zoonoses-related pandemics and consequential global public health crises (Carlson et al., 2022). This toxic combination of climate crisis and public health emergencies has potentially dire consequences for the world's most vulnerable peoples in lower- and middle-income countries (LMICs). At the same time, this era of instability with respect to public health matters is, somewhat paradoxically, accompanied by unprecedented innovations aimed at tackling elements of the cojoined problem.

Since LMICs suffer the effects of public health catastrophes to a greater extent than rich countries (Bernstein et al., 2022), it is imperative that the benefits of public health innovations are deliberately and sustainably extended to LMICs. Accordingly, the focus of this paper is on the current prevailing narratives of governance, via regulation, of public health innovations and their benefits, within the contexts of the COVID-19 pandemic and pursuit of UN Sustainable Development Goal (SDG) 3: Good Health and Well-being (UNDESA, n.d.).

However framed, regulation is a critical and under-addressed (albeit ever-present), multi-pronged tool for enhancing and/or undermining equity in extension of innovations and their benefits. Regulation intersects with the socioeconomic and cultural contexts necessary for extending, or obstructing, access to innovation by those in direst need. Regulation of innovation—or, more accurately, regulation *for* innovation—in the domain of public health requires open-ended interventions at the intersections of, inter alia, law, science, technology, economics and politics (Butenko & Larouche, 2015).

II. COVID-19 and Intellectual Property

When the World Health Organisation (WHO) declared COVID-19 a global pandemic (WHO, 2020), there were, accordingly, concerted efforts at global, regional, national and local levels—across complex strata of policymaking, regulatory intervention and implementation—aimed at containing the virus. Cumulatively, those efforts constituted opportune (even if at times inadvertent) experimentation with respect to the role, potential, and failure, of regulation in a pandemic context. Responses to COVID-19 involved interplays among an intricate universe of regulatory tools focused on access to medicines, specifically access to vaccines and other COVID-19-associated medical technology innovations—e.g., ventilators, intubation devices, medical masks of varying grades, innovative diagnostic tools, diverse sanitary and public health supplies—and services along these innovations' value chains.

The regulatory interventions in response to COVID-19, and the narratives that emerged with respect to COVID-19-related innovation—i.e., proprietary v. open approaches to the intellectual property (IP)-associated products and services being developed and harnessed by the innovations—provided echoes of the international access-to-medicines tensions of the 1990s. Once again, contestations emerged with respect to the merits of access to innovation and its benefits via a closed, proprietary IP (patent) framework v. open access guided by public goods approach (Maskus & Reichman, 2005; Reichman, 2009). Global responses to COVID-19 revisited these tensions—and, significantly, mapped fresh, innovative pathways of regulatory intervention in a direction that favours active public de-risking of vaccine research and development (R&D) (Fisher et al., 2022), with consequential attenuation and decentring of IP.

The global responses to COVID-19 also produced a perceptible shift in the positioning of LMICs—a shift from LMICs being treated as passive markets for export of pharmaceuticals to being seen as necessary domestic

manufacturing hubs of vaccines and essential medicines (see Kolawole et al., 2024). The extent to which this shift becomes fully realised remains to be seen. Finally, COVID-19 put the spotlight on the ascendency of biopharmaceuticals, and the inevitable necessity of collaborative data generation and sharing in vaccine R&D. Such collaboration has been a boost to open science and to open innovation logic. This logic prioritises equitable benefit sharing and the global public goods approach to innovation in medicines and in life sciences, thus raising a particular regulatory dynamic with implications for the attainment of the UN SDGs.

III. COVID-19 and the SDGs

The disruptive effects of COVID-19 rolled back progress towards numerous SDGs (UNDESA, 2021) and also demonstrated the SDGs' interconnected and organic nature of the SDGs (Fenner & Cernev, 2021). The pandemic's impacts on public health triggered a chain of inequitable outcomes with respect to a range of other SDGs beyond SDG 3, including widening of gender gaps. Women bore the greater pathological burden of the disease and greater effects from the resulting socio-cultural and economic disruptions, thus undermining pursuit of SDG 5: Gender Equality (UNDESA, n.d.). Such disruptions not only generally escalated poverty, hunger, barriers to education, barriers to sanitation, and barriers to decent work and economic growth (SDGs 1, 2, 4, 6, 8, 10); they also imposed these escalations along familiar gendered lines of inequality.

The effects of the pandemic on progress towards SDGs were, unsurprisingly, uneven between developed and lower-income countries. A combination of, inter alia, institutional resilience, technological and industrial advancement, fiscal strength, infrastructural endowment, sophisticated public administration fundamentals, and an educated populace positioned developed countries for better pandemic containment than was possible in LMICs.

This asymmetry between developed countries and LMICs in their responses to COVID-19 was symbolised by vaccine nationalism (Oguamanam, 2020). The lopsided response and outcome were practical manifestations of the "10/90 gap" of global health inequity (Luchetti, 2014). Two years into the pandemic, developed countries were luxuriating in a vaccine glut, with citizens choosing and discriminating across vaccine brands. Some were on their fourth doses. Meanwhile, many LMICs had yet to attain 20% population coverage in vaccination with the first dose, notwithstanding high levels of vaccine skepticism in certain countries.

The COVID-19 experience made clear the need to re-think SDG 3, and indeed the entire SDG framework for inclusive and sustainable development (UNDESA, 2021). Such an exercise would, inter alia, need to give priority to emergency preparedness and addressing the lopsided factors that undermine inclusive and equitable outcomes for LMICs.

IV. COVID-19 and TRIPS

Since the mid-1990s, the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) has heralded the global harmonisation of intellectual property protection (Reichman, 2009). Such harmonisation has incorporated specific policy spaces for accommodating the particular needs of LMICs in respect of access to essential medicines. TRIPS concessionary policy spaces, provided to developing countries to mitigate the impact of tightened patents, include: graduated or delayed implementation timelines for least developed countries (LDCs); compulsory licensing of patented medicines for countries lacking domestic pharmaceutical manufacturing capacity; parallel importation of patented medicines; principles pursuant to patent jurisprudence, such as the patent exhaustion doctrine; and other market rules such as market segmentation. Other spaces include national emergency response discretion and circumstances of extreme urgency (Correa et al., 2021).

TRIPS Article 27 arguably strengthens protection of innovation, extending it to all fields of technology without discrimination. TRIPS has also opened the doors for the rise of what analysts have come to call "regulatory property" as a "new form of intellectual property" (R. Feldman, 2016). This notion of "regulatory property" refers to categories of supplementary protections, for pharmaceutical patent holders, based either on market data or on undisclosed test data, e.g., clinical trial data submitted for drug approval. Articles 39.3 and 70.9 of TRIPS entrench data and market exclusivities. Data exclusivity rights confer additional and over-layered proprietary rights to patent holders (Gervais, 2019), with deleterious effects on competition from generic drug makers. In effect, TRIPS escalates the transaction costs of IP, which translates into unaffordable costs of essential medicines for the world's poor, and skewed pharmaceutical R&D priorities and design.

Soon after TRIPS was signed in April 1994 (effective 1 January 1995), the HIV/AIDS pandemic tested the instrument's efficacy as an (in)flexible regulatory framework for access to essential medicines, especially for developing countries (Gathii, 2002). While many in developed countries were able to afford expensive blockbuster cocktail medicines for antiretroviral therapy (ART), HIV/AIDS patients in the developing world bore the brunt of the pandemic because of poverty. This state of affairs starkly reinforced the 10/90 global health gap. Consequently, the 2001 Doha Declaration on the TRIPS Agreement and Public Health (WTO, 2001) was framed to rid TRIPS of the real and perceived obstacles it posed to the ability of developing countries to mitigate public health crises—by optimising TRIPS flexibilities through purposeful interpretational approach to that effect.

The Doha Declaration resulted in the first-ever amendment of the TRIPS Agreement by adding Article 31*bis*. which allows countries without pharmaceutical manufacturing capacity to import, under a compulsory license, a patented drug. To date, Rwanda is the only country to have leveraged Article 31*bis* of Doha, through its agreement with Canada's Apotex Inc. for import of generic anti-viral AIDS drugs in 2007 (Vincent, 2020).

Developing countries have dismally underexploited TRIPS flexibilities (see Deere, 2009), arguably to some extent due to the agreement's fundamental flaws in design and conception. For example, many such countries could do more than they presently do in respect of compulsory licensing and experimental use (and other research exceptions). It was largely in the context of HIV/AIDS that the paradox of intellectual property—as an incentive to innovation and disincentive to equitable access to essential medicines for the most vulnerable—was fully drawn into multi-sectoral policy debate at national and international levels.

With the outbreak of the COVID-19 global pandemic 20 years after Doha Declaration, the existing IP regulatory mediation for access to medicines under TRIPS was revealed to be an abysmal failure. Not only did the system fail to address global health inequity in respect of access to essential medicines, but it also proved to be of little help in navigating a global health emergency. COVID-19 tested in practical ways—and exposed the gains, gaps, and failures of—more than 26 years of TRIPS-inspired regulatory engineering as it relates to public health and access to medicines. Consequently, there has been an active search for a more pragmatic and public-goods approach, now framed around the calls for a special "TRIPS waiver" (Ruse-Khan & Paddeu, 2022; Thambisetty et al., 2022) and the ongoing drama-ridden negotiations, at the WHO, of the anticipated Pandemic Accord. .

V. The "TRIPS waiver"

In 2020, South Africa and India presented before the TRIPS Council a proposal for a "Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19". A revised version of this "TRIPS waiver" proposal was presented in 2021. However, the 12th WTO Ministerial

Conference of June 2022, focused on WTO response to COVID-19 and future pandemics, mostly reaffirmed the core of the Doha Declaration (WTO, 2022). It also highlighted core regulatory imperatives for better pandemic management, including a stable trading environment for goods and services, diversification of production of pandemic-containment goods and services, regulatory cooperation, sharing of regulatory information, recognition of vaccine certificates, and interoperability and harmonisation of digital health applications and technologies. The WTO framed these interventions as voluntary.

The more things change, the more they look the same. In essence, the lack of traction around the TRIPS waiver, and the futile rehash of Doha Declaration by the June 2022 WTO Ministerial Conference, was a clear vote of no confidence in LMICs' aspirations and an affirmation of the failure of the Doha Declaration and operationalisation of Article 31*bis* of the TRIPS Agreement. When the debate over the TRIPS waiver proposal got underway, thought leaders queried the credibility of the presumptive focus on TRIPS, and by extension intellectual property, as the major obstacle to access to COVID-19 vaccines (Thambisetty et al., 2022). Writing in a CNN op-ed, Harvard Law Professor Ruth Okediji maintains that "access to patents alone does not translate into optimal short or long-term ease of access to medicines" (Okediji, 2021).

Like TRIPS Article 31*bis*, the TRIPS waiver debate on the heels of COVID-19 proved intractable as it was bogged down by constraining and counterproductive details. Leading access to medicines campaigner, James Love observed that the June 2022 compromise text of the TRIPS waiver risked entrenchment of TRIPS-plus standards (Love, 2022b) in requiring waiver authorisation to list all patents covered. According to Love, patent profiling is not pragmatic in the context of biologics (Love, 2022a).

VI. WHO Pandemic Accord

The TRIPS waiver debate has since led to a full-blown effort at the WHO through an Intergovernmental Negotiating Body (INB) charged, in December 2021, with developing a pandemic prevention, preparedness and response accord for consideration by the World Health Assembly (WHA). Originally aiming to deliver on this mandate in 2024, WHO Member States quickly learnt that the tensions and dynamic that rendered the TRIPS Agreement hollow with respect to access to medicines in LMICs were not about to disappear overnight through an active, normative WHO intervention.

Since late 2021 when the WHA established the INB, the latter has been a platform for WHO Member States and other actors in their quests to tackle the gaps exposed by the COVID-19 pandemic. The core focus has been on the prevention of future pandemics and the design of effective responses to their inevitable occurrence. Also, the INB has been exploring sustainable funding mechanisms to address the menace of dangerous pathogens. Moreover, and perhaps most importantly, the INB is exploring enhanced regulatory and governance approaches that can minimise distrust, and foster accountability and transparency, in response measures at times of global health emergency.

To date, the work of the INB has reflected complex tensions across both mundane and substantive matters, including the definition of a pandemic and the extent of obligations of WHO Member States who sign onto the Accord. Perhaps most striking, but hardly surprising, is the inflexibility of Member States with respect to potentially limiting their sovereignty in the context of addressing a global public health crisis. The sovereignty question has long been a source of contention for advocates wanting stronger obligations on Member States to take action in terms of the WHO's International Health Regulations (IHR), which are binding on 196 countries. The IHR give premium to state sovereignty, on the basis of which WHO Member States tend to render the WHO's informed public interventions subservient to their national interests even when such interests are patently counterproductive to the global health emergency at hand as was the case with COVID-

19 (Oguamanam, 2024). Paragraph 2 of Article 24 of the Draft Accord that the INB submitted to the 77th WHA in June 2024 reinforces the IHR position that Member States' sovereign decision-making powers must not be undermined. It reads as follows:

> Nothing in the WHO Pandemic Agreement shall be interpreted as providing the WHO Secretariat, including the WHO Director-General, any authority to direct, order, alter or otherwise prescribe the national and/or domestic laws, as appropriate, or policies of any Party, or to mandate or otherwise impose any requirements that Parties take specific actions, such as ban or accept travellers, impose vaccination mandates or therapeutic or diagnostic measures or implement lockdowns.

This draft paragraph is a great set back to those who anticipated that the Pandemic Accord would be an opportunity to revisit the IHR approach to sovereignty. While the work of the INB has succeeded in improving traction for the "One Health, One World" conception, the dominance of sovereignty-focussed thinking remains a significant challenge to the potential of the eventual Accord. The INB is expected to complete its work on the Accord, and submit it to the WHA, in 2025.

There are, at the same time, fractious dynamics in the INB negotiations that reflect the split along the conventional fault lines between developed countries (who dominate technology/IP production) and developing countries. There are really no signs that negotiators are disposed towards transcending these barriers in response to the lessons of COVID-19. Consequently, only time will tell the degree to which the anticipated Accord will mark or fail to mark the much-desired shift from entrenched status quo.

VII. Global public goods

Regulatory tightening of medical innovation through IP protections is symbolised by TRIPS. That strict market model is blamed for the escalation of perennial global health inequity. It also fuels the appetite for a parallel approach to bridge that inequity through open innovation, which does not mutually exclude the application of IP. The open approach acknowledges medicines and medical innovation as global public goods (Maskus & Reichman, 2005). The latter are goods that the IP and market system cannot efficiently make accessible to those in direst need. Those vulnerable populations are mostly in LMICs.

Supply of global public goods requires non-market mediations by state and non-state actors. Analysts have mapped some of these mediations as happening under the agency of non-state actors in complex forms of partnerships with public, private, non-profit and various uncategorised others (P. K. Yu, 2021). This trend underscores the increased prominence of partnership-building—an important and under-engaged aspect of the SDGs, captured under SDG 17 (Oguamanam & de Beer, 2018). Among the tools that these state and non-state actors have developed are advance market commitments, priority review vouchers, and various orphan drug programmes.

IP rights (IPRs) are market-driven reward-and-incentive mechanisms for fostering innovation and creativity. The underlying, but disputed, assumption in this logic is that without intellectual property, the wheels of innovation and invention may grind to a halt or spin at a lower and unhelpful pace. This conventional justification enjoys perhaps the greatest empirical credibility within the patent regime in respect of pharmaceuticals. Despite the inconclusive role of patent grants as stimulants for pharmaceutical R&D (see, for example, R. C. Feldman et al., 2021), a special exception is typically proffered to patents' presumed positive impact on innovation and inventiveness in the pharmaceutical sector.

Focusing on the health sector, as this paper does, requires cognisance of the palpable disconnect between the current pharmaceutical R&D agenda and global public health crises, especially in respect of access to drugs for needy populations, i.e., cognisance of the health sector's exposure of the clear flaw in the reward-and-incentive theory central to the patent system. What is needed is a creative model for access to the benefits of pharmaceutical research—potentially even a global treaty to empower and institutionalise public–private partnerships in health care provisioning. Such a regime would restore balance in the global IP system that presently undermines its public interest considerations (Oguamanam & O'Flaherty, 2021; Oriola, 2019; Oxfam, 2008; Pogge, 2005). To date, the public–private arrangements have tended to focus on drug- and disease-specific interventions, with nothing on the scale of what is required in the context of the global pandemics of the COVID-19 pedigree. And in the first three decades of TRIPS, since its coming into force in 1995, the orientation of creative public–private partnerships has tended to conceive of LMICs as essentially lacking in pharmaceutical manufacturing capacity, and as thus representing merely export markets for essential drugs.

During COVID-19, there were notable shifts on many fronts in approaches to regulatory interventions in support of access to medicines and access to medical technology innovations.

First, there was the proactive and unprecedented de-risking of R&D in vaccines, as evident in the US Operation Warp Speed initiative (Fisher et al., 2022; Okediji, 2021).

Second, there was intense establishment of new ad hoc global partnerships, and funding mechanisms, directed at COVID-19 vaccine R&D and the delivery of various associated medical technology innovations to LMICs. The partnerships include the Medicines Patent Pool (MPP), the COVID-19 Technology Access Pool (C-TAP), the COVID-19 Pledge initiative for mobilisation and sharing of proprietary and other relevant knowledge resources for containing COVID-19, and the COVID-19 Vaccines Global Access (COVAX) initiative—a WHO partnership with non-state actors, most notably the Global Alliance for Vaccines and Immunisation (Gavi) and the Vaccine Alliance, for global supply of COVID-19 vaccines to LMICs.

Third, there has been traction towards infrastructural, regulatory and other relevant capacity development in LMICs in support of domestic vaccine and essential medicine manufacturing, championed by the WHO and a small number of private-sector entities (see Kolawole et al. 2024).

Fourth, there has been increasing recognition of the importance of data both as a tool of R&D and as a collaboratively generated asset. This understanding of the centrality of data provides traction for open science and open access, both of which resonate with biologics as the new gamechanger in vaccine development and, beyond that, in myriad other applications of digital sequence information or digital sequence data in the life sciences.

VIII. Decentring of the patent system

Prophylactic strategies, vaccinology and vaccines remain the foremost, time-tested public health intervention tools (Rutschman, 2022). However, vaccines are rarely candidates for the blockbuster drug market (Rutschman, 2021). They tend not to be attractive for private-sector investment, a situation that makes non-market interventions a significant imperative in vaccine R&D. For example, except for the bold political will of the first Trump administration in directly de-risking COVID-19 mRNA vaccine R&D—through infrastructural support, a subsidised global market, and an unequivocal advance market commitment—it would have been impossible to develop so rapidly the viable candidate vaccines, especially Moderna's (Brothers, 2020). The US government's partnership with Moderna in Operation Warp Speed was instrumental in delivering an historic result.

The success of COVID-19 vaccines is still being scaled globally by WHO, through its push towards global mRNA technology transfer hubs, beginning with South Africa and South Korea, via building infrastructural, skills training, and regulatory capacity for vaccine and essential drugs manufacture in LMICs (Arthur, 2022; Kolawole et al., 2024). The initiative is opportune as it leverages the efficacious benefit of biologics manufacture and at the same time aims to boost the (often elusive) LMIC pharmaceutical manufacturing capacity. The WHO mRNA Tech Transfer Hub programme draws on WHO's 2011 Pandemic Influenza Preparedness (PIP) Framework (WHO, n.d.-a). Through the PIP, WHO Member States collaborate with industry partners and various stakeholders in sharing of influenza viruses with human pathogenic and pandemic prospects, so as to enhance access to resulting or associated innovation, including vaccines and diagnostics to developing countries.

The PIP virus pool includes the WHO Global Influenza Surveillance and Response System (GISRS). This critical data-driven resource is availed, under an access and benefit sharing (ABS) scheme, to entities, including in the private sector, involved in influenza vaccine research, manufacture, diagnostics and accessories. Similarly, the PIP scheme has inspired another initiative of the WHO: the BioHub System established in response to COVID-19 and other recent epidemic outbreaks (WHO, n.d.-c). The BioHub System is mandated to ensure "rapid and broad sharing of pathogens for effective surveillance and the timely development of medical response products such as diagnostics, therapeutics or vaccines" (WHO, n.d.-c). This globally instituted permanent BioHub System is providing a counterpoint to the current inefficient bilateral, and emergency-driven, practice of sharing of pathogens between individual countries.

From the foregoing, the pertinent and intertwined trends associated with the COVID-19 experience can be summarised as follows: (1) the direct public de-risking of vaccine R&D, symbolised by Operation Warp Speed in the US; (2) the escalation of non-state interventions for access to vaccines targeting LMICs, signified by the COVAX initiative; (3) the collaborative R&D and data-sharing inherent in the manufacture of mRNA vaccines and biologics in general; and (4) the WHO's determination to globally scale data-sharing in public health R&D, and the related inclination towards open access and equitable benefit sharing models in that space.

The cumulative effect of these trends is the decentring (and consequential attenuating) of the patent system and its too-powerful role as an instrument of proprietary regulatory control over access to medicines and to health innovation. De-risked vaccine R&D opens up opportunities for attenuated IP claims, providing impetus for boosting local vaccine and pharmaceutical manufacturing capacity in LMICs. It focuses regulatory attention on standardisation, safety, quality control, use of data, ABS, viability of local patronage, and the design of partnership models to ensure sustainability of manufacturing capacity both during and outside of emergency periods.

IX. Regulatory Challenges

COVID-19 has heralded a monumental change in vaccine R&D and innovation, through the introduction of the new mRNA vaccines (Rutschman, 2021). This DNA-based vaccine pathway is dependent on mapping the structure of the genes of a virus and engineering its mRNA sequence so that it can literarily teach the body's immune system to identify and attack the virus (Sheets et al., 2020). mRNA technology is the result of over 30 years of collaborative research by scientific communities, who have developed platforms for making vaccines for conceivably any infectious pathogen by developing and inserting the appropriate mRNA sequence (Brothers, 2020). As biologics, these vaccines are intensely data-driven and interdependent on a

network of multiparty information or data assets, such as trade secrets, which are not easily amenable to patent landscaping.

Notwithstanding the plausible moderating of patents amidst the expanding prominence of data in the new R&D landscape for biologics, it is still the case that leading-edge research methods and tools, as well as non-patent IPRs, will continue to pose new and additional regulatory challenges. In biologics-driven medicines/vaccines R&D and innovation, efficient and timely conduct of trailblazing research requires new research methodologies and tools. Some of these methodologies and tools include expedited access to, processing of, and analyses of, scientific literature and data through, for example, text and data mining (TDM) (Flynn et al., 2021) and direct deployment of artificial intelligence tools. Other tools of advanced research in this new environment involve software-enabled devices and applications, 3- and 4-D printing, repair manuals, and other artificial intelligence and machine-learning operations. At one level or another, TDM and the other above-enumerated tools are crucial for advancing R&D in, and production of, biologics. Of concern is the fact that these applications' deployment and repair could be undermined by copyright (Flynn et al., 2022), and also that in many LMICs there are at present low levels of capacity to use the applications.

As a related matter, trade secrets constitute sensitive business information—often more valuable than the information disclosed in patents, and fully confidential—that is isolated from the information required for disclosure in patent applications. For example, the recipe for making COVID-19 re-agents can be withheld as a trade secret (or as part of the commercial embodiment of the innovation). Without such a recipe, second-comers, including COVID-19 patent licensees, are not able to carry out diagnostics necessary for the containment of the pathogen. As Flynn et al. (2021, p. 12) point out, "[u]ndisclosed knowledge can be a significant barrier to entry for new firms even where authorizations to use patented technology exist".

Trade secrets are likely to assume an increased (and troubling) significance as a tool of choice for firms—a tool that could potentially undermine the coalescing of interests among multiple R&D stakeholders in the biomedical, agricultural, data and related fields towards open science and shared/collaborative innovation models. Consequently, several non-patent and less-mentioned but increasingly relevant regimes of intellectual property require purposeful regulatory attention if they are not to undermine R&D in, and access to, medicines, medical technologies and diagnostics.

X. Research Priorities

The knowledge synthesised in this paper points towards four priorities for developmental research focussed on innovation regulation in support of health and well-being in LMICs and pursuant to SDG 3.

A. Regulation in Support of Ancillary Health Technologies

Global-level emphasis on access to medicines and vaccines blurs opportunities for digital health innovation and innovation in ancillary medical health technologies in LMICs. This is why the 2022 TRIPS waiver is inadequate, as well as why there is skepticism regarding the Pandemic Accord process—given its inclination towards the status quo as well as its reluctance to engage in the iterative process of expanding and updating the regulatory architecture. COVID-19 was and is not about vaccines only. It was and is also about ancillary medical innovations in therapeutics, diagnostics, and accessories. Future pandemics are anticipated to each have their own character, requiring agile and adaptive technological and regulatory responses that go beyond medicines or therapeutics, and that challenge the limitations of sovereignty. Purposeful regulation could support institutional malleability. For example, LMIC innovators not focused on health innovation

could be supported, via funding incentives and other regulatory measures, to pivot their services towards the exigencies of health and other emergencies.

B. Regulation in Support of Social Determinants of Health (SDOH)

There is an opportunity to re-think and more holistically pursue SDGs in order to render LMICs more pandemic- and public health emergency-ready. In addition to emphasis on delivery of essential health care, it is necessary to integrate regulatory efforts to address essential social determinants of health (SDOH) (WHO, n.d.-b)—for example, housing, public transportation, basic hygiene, access to clean water, public health education, social welfare support—so as to render a population more resilient during public health emergencies. In the case of COVID-19, for example, stronger delivery on SDOH would have enhanced adherence to social distancing and other COVID-19 precautionary regulatory measures in LMICs.

C. Regulation of Biologics Innovation for Equity and Inclusiveness

DNA-based mRNA vaccines represent the entrenchment of biologics as a largely data-driven enterprise. Data is collaboratively produced in this space under a networked model, providing a boost for open innovation across life sciences, including open innovation in agriculture, climate mitigation and adaptation, and surveillance of zoonoses' spillovers. Development research focused on regulating biologics innovation for equity and inclusiveness would require exploration of all models of data governance that can enhance equitable and affordable access to medicinal innovation for LMICs. With increased interest in digital or genetic sequencing of data across agriculture, health and other life sciences, options for data regulation, control or management could be inspired by liberal data access concepts—through, for example, compensatory liability models and benefit sharing, as opposed to data ownership.

D. Regulation of Vaccine Manufacture in LMICs

There are disparate partnerships, involving a diverse range of public, private, non-profit and other actors, mediating access to medicines and medical technologies for LMICs. In addition to calling attention on how best to regulate partnerships for sustainable development (SDG 17), this trend reflects the feasibility of political will to de-risk R&D related to public goods. With consequential potential attenuation of IP, this de-risking opens up opportunities for local vaccine manufacture in LMICs. Aside from the core issue of international, regional and national political will to make it happen, the emergent traction for local vaccine manufacture in LMICs raises new regulatory challenges. These challenges include sustainability of new vaccine manufacturing infrastructure beyond pandemic emergencies to address other endemic disease burdens in LMICs; standardisation and quality control; regulatory capacity; and sustainable markets and marketing models for LMIC-made medicines and medical technologies.

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For more information about Open AIR, please visit our website, https://openair.africa, or contact one of our programme managers:
ottawa@openair.africa
capetown@openair.africa

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