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Patents and other conditions of access to vaccines

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Abstract

This paper reviews the experience with access to vaccines during the pandemic. Its inquiry is the extent to which pharmaceutical patents have hindered or enhanced access when compared to other factors or conditions like health spending, manufacturing capacity, and regulatory competence. To conduct the review, the paper queries the regulatory governance perspective when it suggests a decentralised field of legal pluralism will maximise access. It recalls the pre-COVID-19 experience with antiretrovirals to provide pointers to the present situation. It then examines the experience with COVID vaccines under the headings of invention, production, procurement, and distribution. The review finds while patents may hinder access to vaccines, other, essential conditions for access, like independent manufacturing capacity and commitment to procurement, are not established. Regulatory governance must now adopt a much more concerted, coordinated approach, mobilising both patent regulation and other key conditions to further access. The review is an opportunity to gather some of the copious commentary on this issue.

KEYWORDS

access to medicines, COVID-19 vaccines, patents, regulatory governance, TRIPS flexibilities

1 | INTRODUCTION

At the time of writing, late in 2022, vaccines have provided protection against COVID, but many people in middle-income and most in low-income countries have not had access to them.[1] Millions have died, and the virus has mutated. In this context, the inquiry becomes more pointedly what has stood in the way of this access.[2] With an interest in intellectual property, the review is drawn here to the critique of vaccine patents. The waiver of patents seemed a clean solution to problems of access. But how much would it have helped? Was the solution then simply more freedom to operate, a greater pluralism of actors, in other words, a more decentralised, uncoordinated field of regulatory governance? We know that patents also receive a resolute defence.

The review finds that patents did cause problems, and require regulation, but other conditions also need to be met if access is to be ensured. Manufacturing capacity must be spread, regulatory competence developed, and procurement power committed to supply the poor. To this end, producers and governments in rich nations should have done more, but so too producers and governments in middle income countries. In the future, this project requires, if possible, more concerted, coordinated regulatory governance, where international organisations are empowered to compel sensible, collective action. This system would govern both patents and other regulations to ensure timely access to vaccines.[3]

1.1 | The problem of patents

In the pandemic, the critique of patents was revived.[4] According to this critique, giving one actor in this field the legal hold over a vaccine (so far as patent rights extend) raises a barrier to access. The holder is empowered to mount restrictions on the use of the invention and to raise prices for purchase of its product. It constructs a market in which only the rich patients and nations can afford to pay for pharmaceuticals, or they can, at least outbid others for short supplies.

Freeing up patent rights makes it easier to for competitors to develop and produce vaccines, and for procurers to purchase and distribute doses to needy, impoverished populations at home and abroad. Critics enlist the experience with access to antiretrovirals pre-COVID in their campaign against patents.

The TRIPS agreement, which came into force in 1995, spread patent protection around the world. As we know, the Agreement imposed hard law obligations on the many member countries to make patents available for 'any inventions, whether products or processes, in any field of technology'.[5] That obligation included pharmaceuticals, which many countries had excluded from coverage, even if they already had a patents system.

Under TRIPS, the patent holder would enjoy exclusive rights, everywhere in the world, to control the key uses of the invention for a minimum of 20 years; they would become infringements of the patent if done without the holder's authorisation. Drahos warned against this propatent standardisation, citing the economic and social disparities to be found amongst WTO member countries and a world where many patients were still without access to life-saving or ameliorating medicines.[6]

Yet, as we shall see again in this most recent episode, the defence of patents is also strong, and it held its place during the pandemic. In this defence, patents are seen as a vital incentive to engage in research of new vaccines and then a necessary security to invest in production and release the products into markets, especially when they are expensive to originate but easy and profitable to copy.[7] Yes, patents come with exclusive rights, but they do not just provide for stand-alone activities. Providing a clear point of attachment, the proponents of patents suggest, they become an instrument for building the relationships which must fashioned, if vaccines are to progress from research all the way through to distribution.[8] Within this process, for instance, they enable public universities and small and medium enterprises (SMEs) to licence big producers, attach conditions, and receive royalties, then those producers to licence local assemblers and distributors while assuring quality.

Patents might also act as a point of attachment, indeed a clear target, for the private–public governance of access, crucially for regulation of the responsibilities of the holder and the rights of others to research, produce, sell and otherwise deal with the medicines.

Most commonly, patent proponents argue that the patents regime gives others free room to move, frequently termed flexibilities, within and beyond the scope of the patent or, more precisely, where TRIPS is concerned, to authorise the member countries to make laws that allow these others to do so.

Yet, as we shall see, these flexibilities must be activated, often against resistance, and they do not in any case guarantee access. Access may still depend on other conditions being met, including the preparedness of the patent holders to cooperate, for example, by sharing production know-how, and the capacity of others to procure the generic versions.

1.2 | Regulating patents

Some sceptics have taken comfort from the exceptions TRIPS allowed members and the discretions it left them when providing patent protection.[9] Many members were allowed a period of grace to implement pharmaceutical protection and the LDCs continue to enjoy that today. Under article 27 of TRIPS, members were allowed a certain discretion to define the threshold requirement for the grant of a patent, a patentable invention. TRIPS limited the patent period of protection to 20 years, after which competitors were free to supply generics.

Furthermore, article 31 allows in certain circumstances for the grant of compulsory licences to generic producers during the term of the patents, thus overriding the exclusive rights of the patent holder. It was not clear whether these circumstances were exhaustive, and members might have several grounds for granting compulsory licences to local generic producers, such as the unaffordable prices of the patented versions or the lack of local working of the invention to produce them. The Doha Declaration facilitated this flexibility.[10] While the early rulings of the WTO DSB tended to restrict members, the Declaration said members were to be free to make their own interpretations of these provisions. Then, because so many members lacked their own capacity to manufacture, and relied on generic producers in other countries, the WTO constructed the paragraph 6 solution for export under to them compulsory licence, now an amendment to TRIPS in article 31bis.

Thus, such an intellectual property system envisages a role for other actors, not just patent holders. In a variegated field, they range through other researchers, the producers of generics, national governments, health care hospitals, philanthropic foundations, patient groups, and public advocates. Furthermore, during this post-TRIPS period, the right to health has gained a stronger currency, so much, so that patient groups and other civil society organisations put pressure on governments to provide access to medicines.[11] They invoke the right in international and national legal discourse and receive recognition in treaty resolutions and judgements in the courts.[12]

This combination of flexibilities and voices provides opportunities to enhance access, in keeping with the expectations of regulatory governance, to reframe discourse, form new coalitions and find forums sympathetic to access.[13] The view here paints a more complex picture than early pessimistic views, positing multiple actors and competing interests negotiating over access in several arenas.

In this vein, Haunss advised the access to medicines movement to give away its opposition to patents and concentrate its energies on engendering cooperation with the multinational pharmaceutical companies (MNCs).[14] They should, he recommended, use soft law to work with national governments and international donors to encourage the MNCs to help supply these poorer populations by participating in collaborative research projects, patent pools, voluntary licensing, production partnerships and procurement price discounting.[15]

Does the evidence indicate this rally round soft law strategy is enough to get the MNCs to cooperate? The review of the pre-COVID experience finds little evidence that it does so and this reality suggests that, post-TRIPS, the producers of generics and the local manufacturers must comply with the conditions of the MNCs if they want to find a place in the markets. If they cannot form alliances with the MNCs, the generic producers must aim to

produce, independently, medicines which sell in the high-income country (HIC) regulated markets after the patent has run its term.[16] On occasions, the producers of generic medicines might be permitted to make supplies for the poor in low-income countries (LICs), but they must not exploit the technology to divert the products and compete with the MNCs regionally or in the more affluent markets.

It seems the soft law strategy does not obviate the need to pursue the hard law of patent rights. Reviewing results in the key producer country, India, Halliburton asks; 'What are we to make of the fact that two of the ARVs in the Patent Pool—two medications that are the basis of probably most of the voluntary licensing agreements, tenofovir and abacavir—were not awarded patents in India?'[17] This finding seems to suggest that national governments and international donors do need to threaten and at times exercise the existing public health flexibilities of TRIPS (and resist their suppression), so that the MNCs have greater motivation to provide the poor in all countries with access to medicines and secondary producers have more space to assist.

Yet, the review here of the pre-COVID experience suggests this pursuit of legal flexibilities has also proved inadequate.[18] Sekalala was of the view that governments and civil society groups in developing countries find the hard, international intellectual property law to be intimidating.[19] Helfer's conclusion was that: 'Highly contested international rules constrain, rather than expand, the policy space available to governments when those rules are transposed into national and subnational legal systems and can be invoked by competing groups of domestic actors'.[20] With command of legal resources, and support from home and host country interests, MNCs contest the flexibilities vigorously.[21]

On occasions, the flexibilities are asserted, nonetheless the right to affordable medicines should really be a right that the state guarantees, not one that has to be fought for in the courts and legislatures by advocacy groups on a case-by-case basis. Neither should it be met from national budgets and international funds at full patent prices, unless the MNCs choose voluntarily to discount their prices or license generics. Yet they appeared to be the options the European Union offered members when it opposed India and South Africa's proposal for a patent waiver during the COVID pandemic.[22]

1.3 | Beyond patents

The inquiry cannot rest here, for this sceptical view of the regulatory governance of the TRIPS regime does not necessarily mean that the elimination of patents is the sole solution to access. In arguing for a waiver to patents, the critics were likely to acknowledge that a patent-free sphere of operation was not enough to guarantee access; it was a necessary but not sufficient condition.[23] Other enabling conditions prove vital too.

For the review, we may hypothesise several other conditions to be vital, yet quite commonly unfulfilled. They include: (a) public and philanthropic investment in research (especially, to invent medicines for nonwestern diseases and illnesses which are leading causes of mortality in developing countries);

(b) development of local manufacturing capacity outside the advanced economies and even outside the BRICS (which have been the main source of generics), especially in the LICs, but ideally in all countries that have depended on imports;

(c) an ongoing commitment to pay for the procurement of both brand name and generic medicines for the poor, not just by the international donors and the rich nations, but also by the national governments of poor patients, including the many governments which have failed to adequately devote their procurement powers and health budgets to ensuring their access;

(d) the infrastructure to distribute medicines through to patients, some hard to reach in geographical areas or cultural enclaves; and

(e) the regulatory competence, not only to play the patent game, but also approve new medicines for safety and efficacy, flex procurement powers to get them cheaply, and administer competition policies to eradicate restrictive practices like drug cartels and licensing restrictions.

Much of this ground must be made, ultimately, by the key actors. This means the MNCs, who are making profits from the intelligence of many contributors and from the purchases in protected markets. But it must also include the national governments, which often seem to care most for their own kind, if they care for anyone's health. What, then, can regulatory governance do, if the review finds these actors are falling short of providing access to the many who cannot look after themselves, even though the evidence suggests their vaccination would benefit the rest of us too?[24] What could it do to ensure the world is set up to respond properly the next time there is a regional or global pandemic?

To hypothesise, the priorities would seem to be twofold: regulatory governance first to foster genuine partnerships to build local manufacturing capacity and second to commit funds to pay for the administration of doses. These initiatives should be mounted on a collaborative basis rather than come as sporadic and unilateral gestures in the right direction. They need to be concerted and coordinated. The MNCs (often dubbed 'big pharma') require motivation to cooperate with production and procurement, and the threat of relaxing their patents may play a role here, but so too national governments should not be allowed to avoid their own responsibilities to their own citizens or the poor of the world for their health.

The review turns now to the pre-COVID and post-COVID experiences, on the alert for indications of regulatory governance's potential to promote such initiatives, whether that be with or without patents. Its method is empirical then, looking at the record, as best it can, rather than simply theory and hypothesis.

2 | PRE-COVID EXPERIENCE

The COVID pandemic's demand for vaccines came in the wake of a long struggle over access to antiretroviral treatments and inhibitors of the terrible AIDS virus. This part reviews the pre-COVID experience, looking for pointers to what to expect from the response to COVID.

2.1 | Patent-free antiretrovirals

When recounting the experience with the HIV/AIDS virus, after allowing for invention in the north, the focus has been on the considerable success producing and procuring cheap generic first-line antiretrovirals (ARVs) for the poor.[25]

That means the focus is primarily on India. Before 2005, when India was obliged to meet its WTO commitments to TRIPS, the national patent legislation excluded pharmaceuticals from patentability.[26] The onset of TRIPS was expected to limit the access of the poor to second and third-line ARVs, unless other factors come into play, such as voluntary licensing and price discounts, use of the TRIPS flexibilities, or the preparedness of national governments and international donors to recognise the right to health and meet the higher prices.

The first ARV was very expensive and yet, despite pressures and protests, Burroughs Wellcome refused to concede. When other ARVs appeared, prices remained too high for the poor.[27] Into this gap came the family firm, Cipla, when the originating companies, GlaxoSmithKline, Bristol-Myer-Squibb and Boehringer Ingelheim, also refused it licences to produce their ARVs. Cipla worked from their inventions but contributed its own design expertise and processing know-how to produce the three-part ARV cocktail. Cipla's product was around 150% cheaper than the original by Boehringer Ingelheim, and its entry brought access to many poor patients, both in India and in countries abroad such as those in sub-Saharan Africa.[28] This patent-free first-line ARV is still the main source of supply today.

Freedom from patents is considered a crucial factor in this access success story.[29] Other factors played a part too, including the Indian national government's support for a domestic manufacturing industry, such as training of personnel, grants for development and protection from foreign takeover. Even the generics are too expensive for

some patients and into this breach, when we move from production to procurement, came international donor funds, starting with the Accelerating Access Initiative and then the WHO's Global Fund to Fight AIDS, Malaria and Tuberculosis (Global Fund) with support from rich national governments such as the United States' President's Emergency Plan for AIDS Relief (PEPGAR) and philanthropies like the Clinton and Gates Foundations. Even in India itself, the national government National AIDS Control Programme IV (NACP) has relied heavily on these donors until quite recently.[30]

Then, among other crucial factors, health workers would still have to get the medicines out to clinics near those afflicted, some in remote areas, while persuading people to take precautions and prevent infection, to themselves and to others, like wearing condoms and changing needles.[31]

2.2 | Patent protected antiretrovirals

The success started to pale as patients developed resistance to the first-line ARVs and they experienced harsh side effects. In the North, the MNCs patented much better second and third-line inhibitors. Their prices were high. In the post-TRIPS patent regime, access now depended on recombination of factors, including the propensity of patent holders to license voluntarily or tier pricing, the experience of activation of the TRIPS flexibilities, the continuing viability of generics companies and government laboratories, and the procurement commitments of national governments and international donors. In such a field, access would vary from medicine to medicine, it would increasingly be case-specific.[32] Patents would clearly condition how those factors operated, but other factors needed attention too.

As to the play of these factors, the review begins with voluntary licences. Post-TRIPS, the big producers took advantage of the spread of their patent rights; they did not offer voluntary licences.[33] So, as a rule, the generics producers no longer enjoyed the freedom to operate unilaterally. Increasingly, they oriented their production and supply to the more lucrative HIC markets. They built up competence to navigate patent laws and regulatory approvals in these jurisdictions. Sometimes they got assistance, like fast-track approvals, from the authorities concerned about the high cost of brand name pharmaceuticals for their health budgets and their poorer citizens. But they had to face litigation from patent holders to keep them out of the market, even on the expiration of the term. As well as infringement proceedings, brand name producers used patent linkages to regulatory approval to delay generics[34] and sought to 'evergreen' their blockbuster drugs with new patent applications.[35]

The practical strategy for generic companies became collaboration with the MNCs, to become for instance the authorised generic producer on the patent holder's own terms.[36] The MNCs appreciated the capacity of these companies and began to buy them up as well as to produce their own generics.

This shift made the poor even more dependent on sharing a 'community of fate' with the afflictions of the affluent.[37] Priority would go to those which threatened them, often noncommunicable diseases, and the poor would need to rely on excess stock being produced and sold at a discount under tiered pricing schemes. Even so they needed a third party to procure their medicines. National governments were put under pressure to meet the costs, and some were indisposed to use their procurement powers to do so. Some paid high prices, others left the poor to their own resources.

As the epidemic proceeded, the big producers and the international donors wanted the MICs to do more for themselves.[38] While they have large indigent populations, they also have rich elites and burgeoning middle classes. Yet they devote small percentage of their GDP to public health expenditure, especially for the poor. India provides a difficult case. Though India is not a MIC, the country's commitment to public health spending has still been low on a world scale;[39] and its public procurement is fractured between states and hospitals.[40] It has had some success with vaccinations.

Increasingly, under these conditions, the international funds would focus on the LICs. There were still positive initiatives, notably when in 2017 the Global Fund and UNAIDS sponsored the HIV/AIDS first and second-line

treatment dolutegravir (DTG) for sub-Saharan African countries.[41] Under this cover, GlaxoSmithKline (GSK) and Pfizer licensed production at Mylan Aurobindo laboratories in South Africa. Nonetheless, this kind of external assistance would always turn on the preferences of wealthy philanthropists and the politics of national governments. The funds were also now reliant on the strategies of the big producers and the flexibilities which TRIPS allowed. Prices were rising, and they were not prepared to bypass the patent regime to go straight to the generic producers.

2.3 | TRIPS flexibilities

To Shadlen's experienced eye, the openings the TRIPS flexibilities provided were not going to be sure or substantial enough for a go-it-alone generics strategy.[42] To work the flexibilities, the producer of generics would have to find a legal opening both in their exporting home state and in the importing host states. As a major exporter, the Indian experience has rightly attracted much of interest here.[43]

The Indian Government seemed to embrace the flexibilities. It took advantage of its 10-year period of grace under TRIPS to make patent protection available. Among its reservations, it chose not to extend pipeline protection to existing drugs in these 10 years between 1995 and 2005 before full patent protection came on stream.[44] Its legislation was amended to insert the section 3(d) check on applications to evergreen the drugs coming off patent.[45] It provided for pregrant and postgrant opposition proceedings. It strengthened its compulsory licensing powers considerably. It took up the allowance for licensing in certain health emergencies. Its grounds for licensing extended to high prices and the absence of local working of the invention. Licences could be granted for export abroad to countries without manufacturing capacity.

Yet attempts to use these flexibilities attracted a concerted response from the big producers and their home governments. The US Government made representations and the US Trade Representative placed India on its priority watchlist.[46] Crucially, the MNCs used India's open domestic legal system to delay, overturn and exhaust the patent authorities, the generics producers, the patient groups and the cause lawyers.[47] They pleaded various substantive and procedural grounds and moved between forums seeking favourable decisions.

Regulatory governance took heart when two prominent cases ended with legal wins for the opposition to patent protection. These were treatments for cancer, not HIV/AIDS. The first was when the Supreme Court upheld the Controller of Patents decision to reject the Novartis application for a patent for a leukaemia treatment, Glivec, because of 3(d).[48] It cleared the way for the manufacture of generic versions. In the second case, the Supreme Court upheld the Controller's decision to grant a compulsory licence for local production of Bayer's patented treatment for liver and other cancers, Nexavar. Again, generic versions were produced.

So, gains were made, but only by negotiating the system on a case-by-case basis. Local generics producers and patient groups found it demanding to screen the applications being made for drug patents systematically and mount substantial oppositions.[49] As Halliburton found, they did intervene successfully against several second and third-line ARVs, with Gilead Sciences then licensing local production and entering the Medicines Patent Pool (MPP).[50]

While it had undergone a modernisation, the Indian Patents Office still often relied on the major Northern offices to provide a lead in determining patentability.[51] Early studies saw little use of 3(d), however, by 2018, a study found the Office had become more confident in applying it to applications, so too the criteria of novelty, inventiveness, and utility.[52]

To ease the cases, the Indian Government did not firm up the words of 3(d), even after the Supreme Court gave it an encouraging reading: that it required the applicant to show the revision enhanced the drug's therapeutic effect. It failed to heed advice to streamline proceedings for granting compulsory licences, saying no new norms were needed.[53] The Government lost interest in granting compulsory licences.[54] Several applications to licence ARVs were rebuffed.

Previously, countries like Brazil and Thailand had developed an HIV/AIDS strategy and invoked these powers to obtain patent-free generics from India.[55] Now, compulsory licensing became a sporadic affair.[56] In India, the Controller found the patent holder was entitled to due process before a decision was taken to grant a compulsory licence to supply generic versions of Pfizer and Hoffmann-La Roche patented ARVs to Nepal.[57] The application was withdrawn, while it was reported the patent holder subsequently made doses available cheaply.[58]

Nor did the WTO revisit the compulsory licensing provision itself, despite the lack of clarity and consensus round the scope of the grounds it permitted members to legislate for supply domestically. It relied on the Doha Declaration. While allowing export under a compulsory licence, the paragraph 6 solution created a raft of conditions to protect the rights of patent holders. Exporting countries for example have been required to take special measures (such as marking and labelling) to make sure that drugs would not be re-exported to affluent country markets.[59] The WTO did not seek to reform these requirements, even though member countries were saying they were too complicated to be implemented.[60] They were invoked once, in 2007, for the supply of second-line HIV ARV, TriAvir, between Canada and Rwanda, the Canadian company struggling with the local legislation of the requirements.[61]

In declining action on compulsory licensing, the Indian Government said it was time to adopt the Washington consensus approach to correct for abuses of patents and market power such as the use of competition policy measures.[62] The Government resisted the imprecations of free trade agreements and other invitations to install further TRIPS-plus protections locally, such as extensions to the term of pharmaceutical patents, test data exclusivity,[63] and patent linkages to regulatory approval and market entry of generics, which the patent holders might deploy against competitors. But it did not use competition law to regulate the closer collaboration between the MNCs and local generics producers; perhaps it saw a national benefit forthcoming from this strategy.

Other countries found it difficult to apply competition measures too.[64] In one instance, the South African Government famously threatened to apply its competition policy provisions if the MNCs did not grant licences voluntarily to local manufacturers.[65] At the time, the returns were limited. The licences were restricted territorially, and South Africa did not become a regional hub for production of cheap medicines. Its own Government's commitment to HIV/AIDS elimination was marred by obfuscations and lacunae. It chose not to use its compulsory licensing powers.[66] Nonetheless, as we shall see, its initiatives did help ensure there was some local manufacturing capacity on which to build.

3 | COVID EXPERIENCE

3.1 | Invention

The pre-COVID experience was not encouraging, so now we ask whether progress has been made during the pandemic. The experience first with invention, that is, research and development of vaccines, displays the many sides to increasing access. There were to be many various contributions to the vaccines, and some disputes over attribution, yet the patent rights to produce and supply ended largely in the hands of the MNCs.

While the pandemic spurred a frenetic race to make a COVID-19-specific vaccine, the invention built on the substantial legacy of research into coronaviruses pre-COVID.[67] That research included the work on a vaccine against SARS, though tellingly that research subsided when SARS was dissipated.[68] Much of this research was conducted in research universities and institutes with public funding, such as Oxford, Harvard and Pennsylvania universities, while work on vaccines fell out of favour with the MNCs.[69] Philanthropic foundations also filled the gap, especially in the search for vaccines against illnesses that (today) only afflict those in poor countries.

By March 2020, there was a pandemic which could spread right around the world defying attempts to close state borders and private gates. The search for vaccines was given a kick start when a doctor from China put the sequence of the virus on the web. Most of this research was done in dedicated research teams situated within

the regional science hubs of the advanced western economies. There were individual inventors whose efforts were to be feted, such as Sarah Gilbert and Catherine Green at Oxford[70] and Kariko Katalin, Ugur Sahin and Ozlem Tureci at BioNTech.[71] Moderna was to draw on university scientists with the National Institutes of Health. They were quickly joined by research teams in Chinese and Russian laboratories.[72]

It was not until later when they failed to get the licences or supplies that they wanted from these centres, that other countries with their own science capacity, such as Singapore and South Africa, tried to develop their own versions. A WTO staff study shows that the patents were obtained first on applications to the offices in the United States and European Union,[73] though of course they could be multiplied through WIPO's Patent Cooperation Treaty and applications to national offices in other countries too, wherever protection from local or import competition was needed.

More to the point, the WTO study finds most of the COVID-19 patents were taken out in the private sector. Within this sector, many were granted to SMEs. But this survey covers all sorts of COVID-related treatments and technologies. The world was left with two competing vaccines, from AstraZeneca and Pfizer, for the crucial onset period of the pandemic, before Moderna, Johnson & Johnson and others came up to speed, apart from the unapproved Chinese and Russian versions. These companies did pursue patents.

Some applications were slow to be processed, and development proceeded without full resolution.[74] But patents were not irrelevant. Their appropriation was the backdrop to other production and procurement decisions. While, at this stage, the patent landscape was not settled, early patents had been granted, more applications were forthcoming, and infringement disputes had commenced. Thus, a patent thicket was forming, making it difficult for independents to feel freedom to operate.[75] While they were competing, companies were also fighting for control of the technologies.[76] In August 2022, Moderna sued Pfizer and BioNTech, alleging infringement of its patents. It also obtained patents in South Africa and threatened the independent South African venture.[77]

So, while patents were by no means the only driver of development,[78] the claims helped identify which companies to fund for late development and advanced supply of vaccines.[79]

We know that innovation involves implementation and commercialisation as well as discovery and invention. A promising drug must be put through clinical trials and regulatory approvals while being translated into a workable production line and supply chain. Not all inventions are easily replicable, their realisation depends additionally on assets like processing know-how, complementary technology, manufacturing infrastructure and investment capital.[80]

This command of assets may have been another key reason why the University of Oxford was convinced (by the Gates Foundation) to partner the British-Swedish producer, AstraZeneca, exclusively, with its viral vector vaccine, rather than licence all comers.[81] It could also explain why the SME BioNTech gave its licences for the ground-breaking messenger RNA (mRNA) vaccine to Pfizer, a producer with which it had already been collaborating.[82]

Yet while the MNCs boasted these assets for other medicines, they were to receive huge sums of public money to ramp up the production of COVID vaccines. National government payments provided the essential immediate pull for this late-stage development.[83] In Operation Warp Speed, the US government gave Pfizer, Moderna and Johnson & Johnson billions of dollars in development grants and/or advance purchases.[84] Oxford/AstraZeneca received subsidies from the UK Government, the European Union and the United States.[85] The companies were also assisted with fast-track regulatory approvals.

Yet these governments did not insist as a condition of this crucial support that the companies reduce prices or transfer technology.

3.2 | Production

The critique of patents is often concerned with the space allowed to the producers of generics once the medicine has been invented. We have seen from the pre-COVID story how Cipla took the ARVs from the MNC inventions,

themselves based on public research, and improved and expanded their supply. If production is confined to the originating countries, then other developing countries, if they are to gain access to supplies, are obliged to tap into imports from generics as well as brand names. As we see below, this geography affected the pattern of production and distribution of COVID-19 vaccines.

If only because supply chains were disrupted by the pandemic itself, it made sense for these MNC patent holders to license local manufacturing facilities in other countries. Pfizer located its production in the United States where it was based and funded, and then opened a plant in Belgium at the invitation of the European Union when this market grew.[86] At this point, it did not license more widely.

AstraZeneca was not as big a producer and its viral vector vaccine was easier to replicate independently than the new mRNA technology. AstraZeneca licensed manufacturers in Britain and Western Europe where it had received support for research and development and where its first major purchasing agreements were sourced. Then it reached further, licensing manufacturers in some 10 or so countries, including CSL in Australia, Siam Bioscience in Thailand, and SK BioScience in South Korea.[87] In a major outreach, AstraZeneca licensed the big established vaccine producer, the Serum Institute of India, to make doses (along with Bharat Biotech), not only for supply domestically within India, but for export to other countries around the world through the facility COVAX (COVID-19 Vaccines Global Access) as Covishield.[88] Through advanced market commitments, under the aegis of the Gavi Alliance and the Gates Foundation, the Institute had worked with northern companies to produce other vaccines.[89]

This voluntary licensing was selective.[90] Licensees would need to prove production capacity, even if they were confined to a 'fill and finish role'.[91] Their governments would need to provide good offices and local funds. So, even these host countries were to rely on procurement of supplies from Britain and Western Europe in these early days of the pandemic.

As we have seen, certain countries had developed their local medicines manufacturing capacity during the HIV/AIDS pandemic, such countries as Brazil, India, South Africa and Thailand, modifying their patents laws in the process to facilitate this strategy.[92] But then, for various reasons, they had eased off, while others had continued to rely solely on imports. They now had ground to make, if their governments were interested in capacity building for supply to indigent populations at home or abroad. This was especially so for the new mRNA vaccines. It took most of a year for Australia to get local production of AstraZeneca going in the privatised Commonwealth Serum Laboratories (CSL) and the Government had to launch a new long-term local production strategy for mRNA with Moderna as a partner.[93] Other countries remained at the planning stage.

Into the initial gap came the states which were prepared to back their own invention and production, China and Russia. Their vaccines, Sinovac, Sinopharm, and Sputnik V were released early for domestic populations. But they were also taken up by hard-pressed countries like Indonesia. Their presence in the world certainly expanded access, it may also have goaded Western governments, geo-politically, to push for wider access to AstraZeneca, Pfizer, Moderna, and others. These vaccines contributed to the efficacy issues, immediately in terms of the degree of protection they offered the inoculated, longer range in terms of their acceptability at borders as the vaccinated sought to travel.

Could regulatory governance provide the essential grease for this missing technology transfer? Under the TRIPS regime, transfer would need the cooperation of the patent-holding producers (and their partners) but perhaps the international organisations could impel them to do so.

In May 2020, WHO joined with established agencies (Gavi, the Global Fund, the Gates Foundation) to construct the COVAX supply vector. It could see that production would be a hold-up point, at least in the early stages of limited vaccines and limited doses, so it included a manufacturing taskforce. Drawing on the resources of the MPP, it initiated, with the Costa Rica Government, a facility called C-TAP (COVID-19 Technology Access Pool) (Agarwal 2021).[94] Many countries subscribed to this project, but the facility languished until well into the pandemic, when Pfizer came under pressure to cooperate. Pfizer was arguing that companies needed know-how for production capacity, not just patent licensing.[95] In any case, it said it feared an open slather would lead to a

scramble for raw materials which would only dissipate capacity. It would supply the finished product from home countries. But many countries that by this stage preferred Pfizer over AstraZeneca could not get access to these offshore supplies (see below).

In July 2021, responding to this stalemate, urged on by its independent review panel,[96] the WHO instigated a plan for a mRNA vaccine manufacturing hub. Initially designed to partner with Pfizer, it would be built around the producer Afrigen Biologs and Vaccines in Cape Town, South Africa. After Pfizer refused the WHO's request to transfer know-how, the other partners decided to go it alone, constructing a mRNA vaccine from publicly available Moderna data.[97] The vaccine would be made for supply in South Africa and other African countries. WHO would partner with the MPP and the South African and French Governments to support this development.[98]

The WHO's plan was more ambitious. The hub would have spokes. It would link with pharmaceutical facilities in 15 other countries to develop production capacity across Africa, Asia, Eastern Europe and South America.[99] WHO is also promoting capacity building elsewhere, such as a training hub in South Korea.

Then, in November 2021, Pfizer made an agreement with the MPP to license the experimental oral vaccine, nirmatvelvir (together with ritonavir).[100] The MPP called for expressions of interest. In March 2022, Pfizer, through the MPP, made a partnership agreement for 35 selected companies to manufacture a generic version of this mRNA vaccine.[101] These were companies which Pfizer considered could achieve the necessary production capacity, regulatory compliance, and international standards. The companies were situated in some promising locations, including Bangladesh, Brazil, China, India, Mexico and South Africa.

Under the terms of the licences, they would not be required to pay royalties to supply locals while the WHO's pandemic emergency declaration remained in force. They could supply abroad provided they paid a fixed percentage royalty. After the emergency subsided, they would pay a royalty depending on whether supply was to a LIC or MIC. The agreement took in 95 LIC and MIC countries on the Advanced Market Commitment list.

Moderna had signalled it would not enforce their patents while the pandemic persisted. It undertook to build its own plant in Kenya. Johnson & Johnson licensed Aspen HealthCare in South Africa. But, crucially, these outreaches, like Pfizer's licence to Biovac in South Africa,[102] would only be for assembly (fill and finish), after production back in Europe, and would not involve the transfer of the necessary production process know-how and technology.[103]

While expansive, these plans to manufacture more locally could be read as a move to make competition from independent producers in these countries a less attractive proposition. Meanwhile, a Moderna partner threatened the independent WHO hub with patent infringement,[104] and Moderna likened its reverse engineering to the production of high fashion counterfeits.[105]

3.3 | Procurement

These invention and production realities meant patients and their sponsors were vying for supplies from just a few sources and not just because of patents. It was procurement that brought out the worst in the historic failure of access to medicines. Procurement was marked by vaccine nationalism, which meant in essence the wealthy home countries of the producers took most of the supplies, concerned enough about the pandemic to make supplies free to their citizens. Other strategically vital countries pursued me-first strategies too, notably India.

These governments were prepared to pay to corner supplies from AstraZeneca and Pfizer.[106] While AstraZeneca undertook (at the request of the Oxford researchers) to provide supplies at cost during the pandemic, not for profit, its supplies were limited initially. Then AstraZeneca became associated with a blood clot complication, which while highly unlikely to occur, seemed to lead to some deaths. Many countries reacted badly to this news, delaying or suspending approval, or confining it to certain demographics.

Pfizer became the preferred vaccine. While difficult to store and transport at such low temperatures, it proved effective against the original virus and adaptable to its subsequent variants. Its supplies were also limited. Pfizer insists it was always prepared to supply the vaccine at cost to the poor countries, provided they made it free to their citizens, but it

was not happy for prices to be fixed for other markets.[107] It said it was prepared to supply LICs and LMICs through COVAX at cost, but not if COVAX wanted to be the global hub and regulate prices for MICs and HICs as well. Pfizer and the other companies were to make billions from the sale of the vaccines to these countries.[108]

These factors skewed access. By the second year of the pandemic, some three-quarters of doses had gone to the HICs, while a mere 5% to the LICs and for most of the population in Africa no access. The HICs had used advance purchase agreements to obtain most of the first supplies, then ordered even more instalments, while even smaller HICs, Israel an exception, getting in early with Pfizer, were left behind.[109] Countries like Malaysia and Vietnam which now had some resources to help themselves, could only obtain very small numbers of doses either of AstraZeneca or Pfizer.

Vaccine nationalism was complicated when Britain and the European Union stood off, over AstraZeneca, another manifestation when Italy blocked supplies agreed for Australia. In March 2021, the Indian Government banned exports of AstraZeneca from the Serum Institute to prioritise domestic supplies.[110] The national Government had initially left vaccination to the Indian state governments. but the waves of infections grew.[111] A quarter of a million people died during the second wave of the pandemic in India.

Initial supplies of vaccines had trickled out, however, some of these were taken by the HICs. Now countries like Bangladesh and Nepal saw their supplies delayed.[112] In its initial supply, it is reported, the Serum Institute and Bharat Biotech charged LICs higher prices than MICs and HICs, charges that were above cost price.[113] Meanwhile, the Government held up regulatory approval of the Pfizer and Moderna vaccines.[114]

Pre-COVID, we have seen a few instances of MICs and LICs invoking emergency powers to issue compulsory licences to make essential medicines in local laboratories or to obtain supplies of generics from abroad. No country pursued compulsory licensing now for local manufacture of COVID vaccines, though the pandemic seemed to fit the allowances of article 31 and the Doha Declaration.[115] With so many countries lacking domestic manufacturing capacity, they had to be able to satisfy the requirements of the paragraph 6 solution (now article 31*bis*). India was no longer the ready go-to source. In May 2021, Bolivia made a notification to the WTO for compulsory licensing of the Johnson & Johnson vaccine,[116] but its exporter, in Canada, ran into trouble meeting the requirements of the Canadian legislation, harking back to the Rwanda experience.

Once again, the HICs were pressed to pledge supplies to other countries. They did so first bilaterally in small quantities to favoured nations, some eventually offloading their overstocks before they ended their shelf life. As noted, COVAX had been established to gather and coordinate supplies. Some 189 nations had joined the pledge to COVAX, yet by late 2021 it had only received some 19% of the supplies worldwide.

Part of the problem was the self-interest of India. The Serum Institute was to be the main source of supply to COVAX. The Institute was one of the few producers outside the MNCs with the capacity to meet demand; yet the Institute was subject to its own economic imperatives and those of the government that housed it. But so too its reliance on the one vaccine, AstraZeneca, was a stumbling block.[117] MICs and LICs were among those which suspended AstraZeneca. They were still refusing supplies even in 2022, pleading its short shelf life of 6 months. The South African government cancelled its AstraZeneca orders and sent the supplies it held to other African countries.

In June 2021 under a new Administration, the US pledged billions to partner Pfizer to supply 92 LICS and LMICs identified in the COVAX Advanced Market Commitment. Pfizer was to make this its main contribution. Britain, Canada and Germany also made large pledges through the Coalition of Epidemic Preparedness Innovations (CEPI). At Davos in May 2022, Pfizer promised to supply all its patent-protected vaccines and medicines on a not-for-profit basis to 45 LICs.[118]

3.4 | Distribution

If procurement seemed the biggest failure, even if supplies were obtained, patients relied on governments and others to distribute the vaccines to them. This too made demands on their territorial governments' dedication to

public health, how much they cared about, for instance, their vulnerable frontline workers or their elderly and disabled residents. It also tested their logistical capabilities, the efficacy and ideology of their networks and nodes, especially to bring vaccines to the people in remote areas and cultural enclaves. Some governments had infrastructure in place. Others scrambled to equip, turning to expensive and unaccountable private providers for key channels.

To place the vaccine issue in perspective, it is worth remembering that a successful response especially in the dangerous early months before a vaccine was invented and distributed, depended on a public project of social discipline.[119] While the vaccines came on stream, the isolation of infectious individuals was the greatest challenge to intelligence and cooperation. Governments needed prior knowledge of what worked to stop a virus, such as quarantine of entrants or closing of schools. The response was not helped by the lack of learning from previous viruses,[120] nor by the opposition from ideological libertarians and political opportunists, also the lobby from some business interests such as tourism and hospitality who thought they would do better if kept open.

Of course, the border closures and lockdown measures took their toll on conscientious cooperative citizens too, frontline workers exposed to the virus, workers who lost their hours or jobs, small businesses that had to shut, parents home schooling and working from home, families separated from their relations. Their plight tested the quality of their country's labour laws, social security and public services. Thus, for instance, employment security, income support, hospital services and care facilities were found wanting. The impact was devastating among informal workers in the South.[121]

It was hard too to observe these disciplines in densely populated living conditions of cities and slums. The vaccine was most dangerous to those who were already vulnerable, the elderly, the immune-compromised and the malnourished for instance.[122]

The distribution also encountered vaccine hesitancy and resistance beyond those who had medical reasons for fearing their effects. This pushback also made demands on public resources, the problem going, in Bratton's view, beyond particularised vulnerabilities and sensitivities, to expose a general predisposition to see the virus from a subjective, individual, tribal perspective rather than an objective, collective, social one. It was difficult to get acceptance of the idea, the ethic indeed, that vaccination is not just a personal choice, crucially it is your responsibility to vaccinate (or isolate) to protect others as well as yourself. Such compunction was not just for governance systems like China. And this obstructive disposition can be seen to feed back into the problems ensuring access to vaccines and the reasons why regulatory governance fell short.

3.5 | Governance

What does the record of the response to the COVID pandemic suggest? The experience indicates that decentralisation and pluralism governed again. This contested field provided opportunities for civil society to push for access, but these campaigns were fighting back against powerful obstacles, not just the immediate vaccine nationalism but a legacy of infrastructure and budget neglect. The patent-holding producers could have done much more, but to some degree, they were also corralled by territorial governments when they should have been urged to reach out.

International organisations were active, but their influence was largely confined to creating forums where the MNCs and the national governments of the rich countries were exhorted to do more to ensure access.[123] Yet others were not without fault.

The WHO played a largely constructive and responsible role right through the pandemic. But its plans were initially met with unilateralism or bilateralism and its emergency interventions even came under attack from powerful governments in China and the United States. Repeatedly, it re-entered the field constructing institutional forms to get the real actors to focus and collaborate. Its governance initiatives included the Solidarity Call for Action, the Global Vaccine Action Plan, the COVAX, Access to COVID-19 Tools (ACT) Accelerator and C-TAP

formation, and the Summit for Vaccine Internationalism. Other UN agencies have been active too, such as UNICEF's work on the African Vaccine Acquisition Trust (AVAT).

The WTO has been working constructively with the WHO and WHO in the Tripartite Commission. Their secretariats have worked hard to provide research, guidance and training to member countries through the COVID-19 Technical Assistance Platform, so that the patent regime might be optimised for access to vaccines.[124] For example, the WTO secretariat has met with generic drug makers to explore cooperation to achieve more geographically diversified manufacturing and more equitable access to supplies.[125] Such discussions highlighted the importance of technology transfer and article 66.2.

As the pandemic wore on and the problems emerged, the WHO and WTO joined with the IMF and the World Bank Group in the Multilateral Leaders Taskforce on COVID 19. The patent regime remained a consideration but the LICs needed cash and capital too. Already in debt, the LICs could not get priority access to the temporary drawing rights they needed to meet the cost of the pandemic.[126] A G20 WHO initiative, the Financial Intermediary Fund for Pandemic Preparation and Response, looked ahead to the next crisis.

Meanwhile, separately, on the motion of two members, India and South Africa, the WTO's TRIPS Council started into a discussion about a temporary waiver of patents.[127] Given the hedges built into the existing flexibilities, for compulsory licensing, it was a wide and sweeping motion. When a consensus was required, it met with resistance from certain members, including the European Union,[128] even after the Democrats took office in the United States and backed a limited waiver. The proposers submitted a revised text.[129]

The case for the waiver argued it would cut through the thicket of multiple individual company, country and technology patents.[130] This profusion often frustrated effective use of such TRIPS flexibilities as compulsory licensing.

The India-South Africa submission cast the net wide. Learned articles also suggested the waiver of TRIPS protection would be compatible with other treaties protecting intellectual property, notwithstanding some were TRIPS-plus.[131]

The waiver debate carried on into 2022. In May, the TRIPS Council agreed to discuss a draft compromise from an informal group of ministers, members of the Quad: the European Union, India, South Africa and the United States.[132] It was a cautious restriction on the original proposal, reduced from all patents to only vaccine patents, from all countries to the developing countries, excepting those which exported more than 10% of the world's exports in 2021. It would be up to each of these members to take up the waiver, but they could do so by executive rather than legislative means. These members could export, even if their supply was not predominantly for the domestic market. They would have to pay the patent holders adequate remuneration, but that rate should allow for the impact on equitable access.

In June 2002, the WTO Ministerial Meeting adopted a revised version of this waiver proposal as a Ministerial Decision.[133] The WTO has since discussed extending the waiver to COVID-19 diagnostics and therapeutics.

4 | FINDINGS AND CONCLUSIONS

Conclusions are difficult to draw when the pandemic is still in a state of play. But a crisis provides the opportunity to reform regulatory governance when attention is sharply focused and momentum is riding high. In all the suffering, the COVID pandemic has had the positive effect of jolting international organisations into new strategies. What have been the most promising?

In his early judgement, Tooze wondered if the vaccine blockage was all attributable to law and economics, for he calculates the cost of supplying the whole population around the world was affordable.[134] Indeed, in a rational holistic calculation, the benefit outweighed the cost of vaccination, saving lives and avoiding disruption not only in the poor countries but in the rich and the rest of the world given the mutability of the virus and the porous borders. Like AIDS, COVID was a world-wide virus. In this sense, the rich and the poor did share a community of fate.

So, what confounded access? Putting aside the dedication of the care workers, the response often reads much like a subjective, divisive, even an antisocial one. Could a more concerted, coordinated regulatory governance overcome this postmodern dysfunction?

It does not seem possible to attribute the blockages solely to patents, though it is always hard to determine exactly what might have been, the resources which could have been deployed once patent protection was lifted. This review finds that long-term manufacturing capacity and genuine funding commitment are needed, not emergency releases. The countries which fared the best were those with long-term investments in public health systems,[135] while others suffered with underdeveloped systems or systems that have been reduced and privatised in keeping with neoliberal policies and the demands of debt.[136]

As patents are here to stay, they should be tightly regulated in international and national law. It can be useful to threaten to suspend them. Yet the review finds the TRIPS flexibilities are just too difficult to invoke effectively in emergencies; fine-tuning will not suffice. The WTO has talked too long.[137] The waiver it has now agreed would streamline flexibility after 2 years into one such global emergency. It at least has the virtue of collective action rather than relying on individual countries and it might be a precedent for quicker responses in the next crisis.[138]

Even so, someone must be willing and able to produce and procure vaccines for the poor. That capacity must pre-exist; it cannot be built on the strength of one flexibility. The flexibility only opens a door. India had that capacity, but its companies have had to adapt to the patent regime. Secondary manufacturing capacity must be spread much more widely if the system is not to break down again. The WTO mRNA hub aims to do this. But we must note the Afrigen vaccine is only now at the prototype stage; it is yet to be scaled up.[139]

Unlike some medicines, such as the HIV/AIDS antiretrovirals, vaccines are not so easy to reverse engineer and reproduce independently. Some thoughtful advocates argued for expanding the public disclosure that is meant to accompany patents.[140] They also stressed the need to take the waiver beyond patents to the companies' confidential production technologies.[141]

The India-South Africa submission sought to extend the waiver to TRIPS protection of undisclosed information and test data. The final compromise was confined to patents. But practicalities also stand in the way of forcing technology transfer. The waiver could only apply to codified information, that is, the kind of information that could be documented and consulted independently. Technology transfer also depends on access to tacit information that is embodied in the experience of people and shared on a show-how rather than know-how basis.[142] Its transfer depends on building relationships between willing and competent operators in both developed and developing countries. This kind of transfer depends on cooperative joint ventures.

From experience, Drahos is sceptical the pharmaceutical companies will be party to this transfer.[143] The HIC home states are unlikely to compel them to do so. The COVID experience tends to confirm this finding. Perhaps the pandemic will provoke a change in attitude.

It is futile, Drahos also counsels, to keep seeking support for forced transfer in the international treaties. In the pandemic, Vietnam was reported to be asking for technology transfer to be implemented, but it is not clear where this request has gone. The WTO has taken a very passive approach to the TRIPS technology transfer obligation in article 66.2, though there are signs now it might take a more positive approach.[144] The United States Government has now licensed 11 research tools and early-stage vaccine and diagnostic candidates to the MPP through C-TAP.[145] But these are public sector, National Institutes of Health, owned technologies. Governments are the subject of WTO requirements, not corporations. Unlike the United Nations, the WTO has not developed a jurisprudence of corporate responsibility in return for its property protections and market freedoms and this is a good reason for it to coordinate governance with organisations like WHO.[146] We might also mention the tendency of free trade agreements to prohibit the performance requirements some countries have placed on foreign direct investment to ensure there is some spin-off for the host economy.

This review finds it is not feasible to rely on any one company or any one government, to supply the world with generics. Even so, if countries seek to invoke the waiver, they should feel obliged to follow through on providing access for the poor.

Ideally, all producers and governments should share in the responsibility to ensure the poor have access to medicines. In the future, they must be prepared to give the international organisations more authority to coordinate this common project. The COVAX supply channel was a worthy project when it focused on the LICs, while WHO has taken a step further in supporting manufacturing hubs outside the major producing countries.

Drahos urges the LMICs to build manufacturing networks between themselves independently.[147] They have shown on occasions they can do this[148] Nonetheless, these countries will have to maintain their research laboratories and manufacturing facilities across unsettling changes in populations, governments and other circumstances, if they are to anticipate fresh pandemics. Some of the spokes in the WHO mRNA network are established facilities, Biofarma in Indonesia for instance, but other locations are starting from scratch.[149]

This review would suggest the new independent manufacturing hubs will continue to rely on subsidies, both local and global, if they are to be sustainable.[150] As the pre-COVID experience indicates, they need to be able to build on an adequate guarantee of procurement in the future. They will need international support, as much financially as legally, in the shape for instance of advanced market commitments from donors, so they can see the necessary demand to sustain development. The South African Government has already called on COVAX and Gavi to buy from Afrigen at the new manufacturing hub in Cape Town.[151] But Gavi has been prevaricating.[152] The host governments must also commit financially.

Furthermore, some countries will not reach production capacity; they will continue to need financial help procuring medicines from other countries. This help cannot continue to depend on ad hoc, unilateral gestures from national governments and private foundations. It needs to be independent of vaccine nationalism, yet the global system still largely depends on national sovereigns.[153] Ideally, a global fund, like the United Nations Global Fund for HIV/AIDS, Tuberculosis and Malaria or even the Green Climate Fund, should be established to anticipate the next epidemic, in part by imposing windfall taxes on those who profit from the crises. The rich and international financing organisations need to back the WHO in this endeavour.[154] NGOs, such as the South Centre, are advocating a new international treaty for epidemic preparedness to give impetus to this support. All governments must endeavour to build up their domestic public health systems.

So, to gather together the lessons from the review: the MNCs have to be pushed to give access; it is too much to expect countries to take up the flexibilities individually; access cannot rely on one country to produce and supply generics, independent manufacturing capacity must be spread; the rich in the HICs and MICs must do more to fund the poor's access to medicines, both at home and abroad; the international organisations should follow through on their good governance work, both marshalling the big producers and governments and enabling the others to play their part.

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The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

All data drawn from published material, most available publicly online, though some media and journal sources cited may be by library subscription rather than open access.

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