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From Internationalism to Nationalism: The Shifty Politics of Pandemic Philanthropy



On January 22, President Jair Bolsonaro tweeted this image to Prime Minister Narendra Modi. The text that accompanied it read: Namaskar, Prime Minister <u>@narendramodi</u>. Brazil is honored to have a great partner to overcome a global obstacle. Thank you for helping us with vaccine exports from India to Brazil. - Dhanyavaad! धनयवाद?.

The choice of words and images are revealing. 'Namaskar' (hello) and 'Dhanyawad' (thank you) are both Hindi words derived from Sanskrit. The Sanskritization of Hindustani into contemporary Hindi (Hindustani draws from both Urdu and Sanskrit vocabularies) has been part of the contemporary Indian right-wing government's efforts to mainstream Hindu nationalism. The image is less subtle. The photo of the god Hanuman carrying the vaccine from India to Brazil refers to the Ramayana myth that has been vital to the consolidation of a chauvinist Hindu national identity. Hanuman's mythological master – Ram – has been a key icon for the Hindu right, as they have rallied to build a temple dedicated to his birthplace on the site of a mosque demolished by Hindutva activists.

This easy camaraderie between two of the world's leading right-wing figures is not in itself shocking. Rather, I am drawn to this image for how it simultaneously resurrects and mutates a long history of global alliances responsive to pandemic crises. Famously, during the height of the AIDS epidemic at the turn of the century, the Nelson Mandela government allied with India and Brazil to export and import generic AIDS therapies. Specifically, the South African government issued a compulsory license declaring a national emergency, thus temporarily exempting themselves from enforcing foreign patents on life-saving HIV-AIDS therapies. This compulsory license had the powerful support of HIV-AIDS action groups across the world, at a scale unprecedented for health activism. In response, a coalition of Euro-American pharmaceutical companies sued Nelson Mandela personally for violating their corporate rights. In the beginning, they were backed by the Clinton Administration, who for their part threatened to raise tariffs and restrict trade. Fortunately, with presidential elections in the horizon, several key US politicians made a dramatic about-turn. Thanks to the South African effort and its alliance with an Indian generic manufacturer, within weeks, the price for HIV-AIDS therapies fell to a fraction of the original cost. Soon after, Brazil approached Euro-American pharmaceutical corporations with a threat of similar compulsory licenses. However, they did not have to carry out their threat; this time, corporations rushed to agree to drastic price cuts.

Bolsonaro's tweet reminds us of this history, not because it is an echo of a past solidarity, but because of the dramatically changed context that has blunted the political edge of such expressions. In September 2020, Oxfam published a widely publicized report about how wealthy nations representing just 13% of the world's population had cornered over 50% of the promised doses of leading vaccines. As they had with HIV-AIDS anti-retroviral therapies, the current South African government termed this 'vaccine apartheid'. Yet, since the time of that pandemic, the possibilities of global south solidarities had dramatically narrowed. Then, under a similar situation of glaring therapeutic inequality, the Mandela government had been able to consolidate support across the global south, leading to contravention of foreign patents forced upon an involuntary Euro-American big pharma. In the present, the closest echo to this

past are calls by global south governments for big pharma to *voluntarily* suspend their patent claims. So far, this approach has proved far less successful than the past strategy of an involuntary enforcement.

Countries' positions on waiving monopolies for COVID-19 medical tools



https://phm-na.org/2021/02/rich-countries-must-join-the-world-in-supporting-the-trips-waiver-to-end-the-pandemic/

The curiosity of the present in relation to the past then is this: the present-day appeal to *voluntary* philanthropy asks for *more* radical concessions than the past *involuntary* compromises forced upon unwilling corporations. That is, the global call for waiving TRIPS restrictions asks these corporations to charitably concede more than they have ever been forced to. To elaborate, a compulsory license enforces an involuntary contract upon a party reluctant to concede its patent claims. Enforcing this contract takes work; each country has to go through its own regulatory process and set up its own bilateral agreements. Even though this opened up radical avenues during the HIV-AIDS crisis, a complete waiver would have been an quicker, all-encompassing procedure that would have possibly saved innumerable lives. But pragmatic about what they could achieve, the South African government followed a plan that was more bureaucratically demanding, but in the end, practical. In contrast, the demand now is for the almost impossible. A waiver requires complete consensus amongst signatories of the WTO-TRIPS, many of which have consistently fought against any loosening of patent restrictions under any circumstances. *Thus, in the present, we have governments and people's health*

movements mobilizing for a radical impossibility rather than a plausible, tried-and-tested possibility. In what follows, I describe how such a situation came to pass and its consequences for global vaccine equity.

To begin with, how did India come to acquire this capacity that undergirds both versions of the demand for global drug equity? The answer lies in patent law. India's first Prime Minister Jawaharlal Nehru's zeal to rapidly industrialize the newly independent nation is well known. This drive conjured into being a pharmaceutical industry almost out of thin air. Key to this transformation were a set of regulatory shifts. In 1957, Nehru appointed a Madras High Court judge - Justice Ayyangar, to overhaul the colonial patent system. Justice Ayyangar had trained under Sir Alladi Krishnaswami Ayyar, one of the chief architects of the Indian constitution who gained the admiration of Ambedkar for his commitment to social justice. Justice Ayyangar submitted his report in 1959, which was finally enacted into law in 1970.

The chief intervention of the Ayyangar report was that it turned a small Indian pharmaceutical industry into a global power. Till then, the captive Indian market had been dominated by Euro-American firms. The Ayyangar report countered this domination by overhauling the patent regime, restricting patentability to the *process* of drug manufacture and not the final *product*. In other words, competitors could make the same end-product as long as they demonstrated that the process through which they had made it was novel. This was a crucial innovation. Recently decolonized, indigenous capital could not compete with long-established Euro-American pharma. However, India did have a large labor force at its disposal. In just 30 years, Indian pharma grew from about 2,200 manufacturing units to 20,000 manufacturing units across the country. This is how the Indian generic industry came into being and by the time of the HIV-AIDS crisis, was able to supply about 80% of the HIV-AIDS therapies distributed by Doctors Without Borders across Africa. It is for this reason that Doctors Without Borders gave the Indian generic industry an honorific that has stuck – 'a pharmacy for the global poor'.

However, the years of postcolonial protections would come to an end in 1995. Under the sign of a finance capital crisis India took a loan from the IMF and joined the WTO. The WTO came packaged with new IP laws, commonly known as TRIPS. TRIPS demanded the reversal of Ayyangar's process patent regime, and a re-implementation of colonial-era product patents. *In effect, this meant that India could no longer produce generic versions of any drug discovered after 1995, for a period of 20 years after the original patent.* Yet, the implementation of TRIPS within the Indian constitution did not complete over-write the Ayyangar report. In 2012, the Indian Patent Controller – P.H. Kurien revisited the provisions that survived this overhaul: in particular, the provisions that allowed for compulsory licenses. The ensuing order forced Bayer to allow an Indian drug maker to copy and sell its profitable liver and kidney cancer drug Nexavar to a domestic market. Bayer of course immediately challenged this decision, ending in their appeal's denial in the Indian Supreme Court in 2014.

I return to this license because it points to a possibility that seems foreclosed in the present crisis. The Nexavar compulsory license is significant not only because it makes an exorbitantly expensive cancer drug available to many more in India, but because as a compulsory license, it fundamentally threatens the global hegemony of big pharma. It is an exercise of sovereignty by a global south government on behalf of its own citizens. If regulators and courts find that an 'average' Indian citizen cannot practically procure a life-saving therapy, a compulsory license changes the rules of the game. It comes as no surprise then that this judgement is front and center of the annual United States government report that lists countries in violation of the spirit of international intellectual property, a list in which India continues to hold pride of place. That compulsory licenses are entirely legal both within the framework of national law and within the international WTO-TRIPS agreement goes unmentioned.

Cut to 2020. In early March, the Coronavirus Appropriations Act was signed into law. The Bill set aside \$8.3 billion dollars for federal agencies to manage the outbreak. Almost half of this amount would go into incentivizing and supporting vaccine production. This massive injection of federal funding could have easily come with the proviso that vaccines produced be affordably priced. The bill did the exact opposite. It put in a clause that the government would *not* raise the question of affordability, on the grounds that such concerns might delay vaccine production. This was the first clue to how the language of emergency would be used. If Indian courts had looked to emergency provisions as a way of ensuring affordability, here the bill did exactly the opposite, giving the up the right to negotiate even before negotiations had begun.

This move did not go unnoticed. Later in March, the Chilean, Ecuadorian and Israeli governments all passed resolutions approving the use of compulsory licenses for the pandemic. While the first two were more pre-emptive and a matter of principle, the Israeli government immediately exercised its right, declaring that it would import a generic version of a promising Covid-19 drug from India. This was the first time that Israel had issued a compulsory license for a patented drug in over 20 years. The drug in question was Kaletra, often used in HIV-AIDS therapies. Its manufacturer - the American company Abbvie - had managed to extend its patent in Israel but had failed the test of novelty in Indian courts. Abbvie responded by declaring that it would not enforce its Kaletra patent anywhere in the world, pre-empting any further legislative moves. At first glance, this might seem to be an act of corporate beneficence. At the same time, just a day before Israel had issued its license, the New England Journal of Medicine published a study establishing that Kaletra had no positive effect on Covid-19 patients. Further, Kaletra is an effective HIV-AIDS therapy. In issuing its Kaletra license, Israel had clarified that it would only import it for Covid-19 and withhold the generic from HIV-AIDS patients. Abbvie's hurried pledge pre-empted other compulsory licenses followed that might have followed Israel's cue, without Israel's promise to withhold it from patients dying from HIV-AIDS, a disease no longer considered a legally-binding 'emergency'.

Let's skip ahead a few months to June, and to the announcement of the most significant global partnership in response to Covid-19. At the Global Vaccines Summit hosted by Great Britain

and Northern Island, representatives from 62 countries, including 42 heads of states and leading pharmaceutical CEOs announced COVAX. The summit raised \$8.8 billion for the organization that would lead this effort. Noticeably, the US did not join the effort. On the surface, COVAX looks like the ideal model for a successful public-private partnership. However, scratching this surface reveals troubling details. COVAX as a loose multilateral agreement does not preclude bilateral deals. Participating governments and corporations remain free to make deals amongst themselves, and many have done exactly that. COVAX's ambition instead is to hope that countries voluntarily wait their turn at this multi-lateral table until every country can cover at least 20% of its population. But not only is this clause non-binding, it specifies that by all countries, it really only means the high-income investor-countries that paid into the program. No such guarantee is made for LMICs; the agreement only offers a vague promise that the highest priority populations within those countries should get the vaccine – with no numbers attached to how much of the population it is meant to cover.

To my mind, underneath all the hype, COVAX seems very similar to the erstwhile Trump government's injection of federal funding into vaccine development. There are no obligations upon corporations or governments, there are no enforceable mechanisms for ensuring equity, and under the guise of philanthropy, corporations stand to make enormous profits. Really, one might ask what the point of a pooled initiative such as COVAX really is, when like the US government, it refuses to negotiate prices with its private partners. Recognizing this, the MSF immediately issued a sharp rebuke to the initiative, revealing that COVAX had been the consultancy firm McKinsey's brainchild, and that they had proactively ignored non-profits like the MSF that have been critical of pharma in the past.

Let us skip forward again, now to early October, when two of the big players in the vaccine scene – AstraZeneca and Moderna – made startling announcements. AstraZeneca pledged to not make profits on the vaccine and Moderna pledged to not enforce its IP during the pandemic. Both corporations have received more than a billion dollars of federal funding to develop the vaccine. The pledge to not to profit makes little sense when their costs have already been taken care of. Further, the AstraZeneca vaccine came out of research at Oxford. Early on, the university had declared its intention to put out their discovery free of charge. They had withdrawn this offer under pressure by the Gates Foundation, one of the university's donors. Instead, the Gates Foundation pushed them into signing an exclusive deal with AstraZeneca. It was at the same time that the Gates Foundation was putting COVAX into place. Oxford's announcement of a free vaccine threatened their carefully crafted plan to create a single global venue for private-public vaccine development over which they would have complete control.

What then about Moderna's claim to license out its IP during the pandemic? This is where things get scientifically interesting. Much of the excitement around the science of Covid-19 vaccines is centered on a completely new platform for delivering genetic instructions to the human body. Moderna's vaccine is based on this delivery technology – through mRNA. To

begin with, the mRNA delivery technology was first developed at the University of Pennsylvania, and therefore funded by taxpayer dollars. Further, despite all the hype around it as a technological breakthrough, the mRNA platform was not even entirely new at UPenn. It has been considered as a vaccine mechanism for several decades, with published papers going back at least to the 1990s. In contemporary reporting, the real breakthrough identified in the mRNA delivery platform is the lipid nanoparticle within which the unstable substance is encased. Enclosing drugs in lipid nanoparticles has been developed at MIT for several decades. Really, the only thing that was holding Moderna back from releasing an mRNA-based product to market was a few hundred million dollars that would allow them to take the last step in a process they had been developing but had not found the right conditions for a rollout. Covid-19 could not have come at a better time; they got more than they could ask for from operation warp speed: over a billion dollars of no-strings attached funding, adding to the undisclosed DARPA and NIH funding the corporation had already received before the pandemic. What the pandemic allowed Moderna was a massive proof-of-concept for their new delivery mechanism at a scale they could only have dreamt of before the pandemic. While they might choose to not profit beyond a certain point in the immediate present, the value of mainstreaming a process that will now be extended to all kinds of lucrative life-time diseases (diabetes and cancer for example) is incalculable.

Further, if we are able to deconstruct the hype around mRNA as a radically new technology, it becomes clear that there is no purely scientific reason that old regulatory strategies cannot work. The most complex and challenging biotechnological processes are still seen as the provenance of the global north; with the global south often seen as an unreliable place from which to procure highly sophisticated bioengineered molecules. However, the reason that mRNA has been so successful is not because it is an unprecedent technological breakthrough; rather, it is because it is a cheaper, faster and more affordable way to deliver harmless parts of a virus to the human body, triggering an antibody response. Thus, there is no technological reason for compulsory licensing to be off the table. That is, there is no gap in capacity between Indian and Euro-American manufacturers; the shortcoming is in a political will to exercise sovereign rights. If it chose to, the Indian state could easily have exercised its right as it did in the past in order to manufacture an mRNA vaccine at scale and cost. The reason that these possibilities seem foreclosed brings us to a phrase that has circulated widely in recent months – vaccine nationalism.

The best way to describe the difference between the political momentum around HIV-AIDS and the political moment today is to contrast a past vaccine *internationalism* with present-day vaccine *nationalism*. In the 1990s, it took a configuration of three states and their allies – South Africa, India and Brazil – to come together to challenge Euro-American pharmaceutical interests. 2020 was a very different year and a very different pandemic. This difference came most starkly into view in the WTO-TRIPS meetings that happened in October and December. The echoes of the HIV-AIDS epidemic still sounded in these meetings – South Africa and India joined together to ask for a suspension of TRIPS provisions as an emergency measure

during the pandemic. But tellingly, Brazil voted against their old allies' proposal, choosing to go it alone in a bilateral deal with AstraZeneca.

In this new configuration, it is the Indian position that is the most difficult to parse. Yes, they showed up at the WTO mouthing the words of global south solidarity. Yes, they have promised to distribute low-cost vaccines to the global poor. But while their enunciations sound similar, the position from which the Indian state speaks has shifted dramatically. To return to the question I posed in beginning this essay, they demanded the impossible rather than the plausible: a waiver of TRIPS exceptions rather than compulsory licenses. To put it differently, the government's position is that they did not want to antagonize global multinationals from doing business in India. Even though compulsory licenses are legal, they have made clear that they would rather seek a voluntary exemption from the entire WTO body. The request for a voluntary waiver rather than an involuntary license demonstrates a dramatically changed political landscape for global south alliances around life-saving therapies. Shifts in political will, rather than shifts in regulatory regimes or technology, seem to be dictating the course of vaccine equity. As for civil society and activist organizations, they seem to have chosen to work within a space already constrained by the Indian government's unwillingness to exert their sovereignty over the interests of global pharmaceutical corporations.

Indian vaccine nationalism today then is a strange and distant mutation of a past idea that it is a 'pharmacy for the global poor'. MSF bestowed that honorific on India not only because it had the manufacturing capacity, but because it had been willing to risk backlash from multinational corporations and the US government. Today, the honorific is hollowed of this radical content. What it means now is that India will go along with the global patent regime, relying on the goodwill of AstraZeneca and the Gates Foundation to allow it to make the number and kind of vaccines they deem philanthropically appropriate. Given the Gates Foundations' commitment to defining the terms of global philanthropy, this blanket permission might not be forthcoming. In a sense then, the Indian government made the most of a complicated situation; inheriting the title of the 'pharmacy of the global poor' fed well into the nationalist government's desire to present the country as a global superpower. However, this desire to flex their chauvinist muscles ran counter to their simultaneous desire to be friendly to Euro-American corporate interests. There was however one way out. To manufacture an 'Indian' vaccine that did not contravene patent rights, that could then be philanthropically distributed to the world as a sign of regional power and generosity. This situation has produced an ethically disturbing answer - Covaxin.

Covaxin is an antiviral developed and made in India with a public-private partnership between the government and a single corporation – Bharat Biotech. It is not delivered through mRNA (like Pfizer and Moderna's vaccines). But it shares a characteristic with mRNA vaccines: it does not need the complex engineering of protein synthesis. Instead, it works like many older vaccines. The vaccine delivers an inactivated version of the coronavirus that is harmless within the body but still produces an immune response. I note its difference because the claim to its 'Indian' discovery and production comes at a cost. While compulsory licenses allow an Indian manufacturer to make a drug already tested for safety and efficacy elsewhere, the government's desire to 'make-in-India' meant that Bharat Biotech had to complete its own safety and efficacy trials. However, such a wait-time would have been politically untenable; it did not fit with the Indian government's desire to produce an image of the country as at par with other global superpowers. As a result, the Indian government decided to take an ethically unprecedented step. It rolled out Covaxin to the Indian public before completing its safety and efficacy trials (the results of the Phase III trial are still being studied at this time of writing). In order for the government to maintain its jingoistic claim that it was both powerful enough to meet its own needs as well as distribute vaccines to the rest of the world, they put the lives of their own citizens at experimental risk. Further, not only did the Indian government make the drug available, they gave its citizens no choice between an already tested drug (the AstraZeneca vaccine voluntarily licensed to the Serum Institute in India) and one that had not been fully tested. This is a fundamental contravention of the most fundamental bioethical norm: that life-saving treatments are not withheld when they are known to be available in favor of another that is still being tested.

To make matters worse, multiplying reports of missteps in data collection have already cast doubt on the clinical trial protocol. For example, activists responsive to the Bhopal Gas Disaster have brought to light how the vaccine was tested on present-day survivors without their consent; they were told that they were in fact being vaccinated. And for their trouble, they would be paid twice their daily wage, an offer too good to refuse for many that had struggled financially through the course of the pandemic. Unsurprisingly, this deal – to be vaccinated before much off the world and to be paid for it – turned out to be too good to be true. This not only casts doubt on the ethics of the Covaxin trials, it also undermines any data that these trials will produce. The hospital conducting this arm of the trial miraculously reported doubling the number of subjects they were expecting to find, while reputed hospitals in Delhi were failing to cover their quota. Many of those that were tested have not been followed up on, violating any possible trial protocol. It comes as no surprise then that the trial protocol and data has been kept secret, even as their successful results are now being reported to the media.

In the present then, any talk of India as 'a pharmacy of the global poor' will have to reckon with its unethical treatment of its own citizens and the untrustworthiness of the clinical trial process that has legitimized its home-grown vaccine. More broadly, with the steady dissipation of global south solidarities that emerged at the HIV-AIDS crisis, a vacuum has opened up. This space is now being filled by private-public partnerships, such as the one between the Indian government and Bharat Biotech and the one between the Gates Foundation and Euro-American corporations and states. These much-publicized partnerships are dangerous because they mask growing inequities with the rhetoric of a 'public good'. To put it simply, they deploy the same rhetoric devised by activists that had threatened the interests of Euro-American

pharmaceutical corporations and states, while disarming the rhetoric's political potency and disarming its strategies. At stake are the hard-fought gains won for global vaccine equity, gains that are being reversed in an effort to maintain corporate and global good will. To be clear, this is not an indictment of people's health movements advocating for a waiver of restrictions; rather, I only wish to point out the circumscribed political possibilities for such activist imaginations, that in the end are forced to reckon with the limits of what global south governments are willing to risk.