## 1AC

### Framework

#### I affirm the resolution – Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### The value for today’s debate is morality, since ‘ought’ implies a moral obligation.

#### The value criterion is minimizing oppression, defined as promoting the material conditions necessary for inclusion.

#### Mitigating oppression is necessary to prevent flawed moral exclusion.

Opotow 11 – Susan Opotow is a social psychologist and justice researcher at the City University of New York. Her research examines the scope of justice over time, as well as exclusionary and inclusionary change in a range of contexts that include: environmental degradation, societal changes after the USA Civil War and World War II, and museums that represent past injustice. She was Editor of Peace and Conflict: Journal of Peace Psychology) “Social Injustice,” Peace, Conflict, and Violence: Peace Psychology for the 21st century, Englewood Cliffs, New Jersey: Prentice-Hall, 2001

Both structural and direct violence result[s] from moral justifications and rationalizations. Morals are the norms, rights, entitlements, obligations, responsibilities, and duties that shape our sense of justice and guide our behavior with others (Deutsch, 1985). Morals operationalize our sense of justice by identifying what we owe to whom, whose needs, views, and well-being count, and whose do not. Our morals apply to people we value, which define who is inside our scope of justice (or “moral community”), such as family members, friends, compatriots, and coreligionists (Deutsch, 1974, 1985; Opotow, 1990; Staub, 1989). We extend considerations of fairness to them, share community resources with them, and make sacrifices for them that foster their wellbeing (Opotow, 1987, 1993). We see other kinds of people such as enemies or strangers outside our scope of justice; they are morally excluded. Gender, ethnicity, religious identity, age, mental capacity, sexual orientation, and political affiliation are some criteria used to define moral exclusion. Excluded people can be hated and viewed as “vermin” or “plague” or they can be seen as expendable non-entities. In either case, disadvantage, hardship, and exploitation inflicted on them seems normal, acceptable, and just—as “the way things are” or the way they “ought to be.” Fairness and deserving seem irrelevant when applied to them and harm befalling them elicits neither remorse, outrage, nor demands for restitution; instead, harm inflicted on them can inspire celebration. Many social issues and controversies, such as aid to school drop-outs, illegal immigrants, “welfare moms,” people who are homeless, substance abusers, and those infected with HIV are essentially moral debates about who deserves public resources, and thus, ultimately, about moral inclusion. When we see other people’s circumstances to be a result of their moral failings, moral exclusion seems warranted. But when we see others’ circumstances as a result of structural vio- 4 lence, moral exclusion seems unwarranted and unjust. Psychological Bases for Moral Exclusion While it is psychologically more comfortable to perceive harm-doers to be evil or demented, we each have boundaries for justice. Our moral obligations are stronger toward those close to us and weaker toward those who are distant. When the media reports suffering and death in Cambodia, El Salvador, Nicaragua, the former Yugoslavia, and Rwanda, we often fail—as a nation, as communities, and as individuals—to protest or to provide aid. Rationalizations include insufficient knowledge of the political dynamics, the futility of doing much of use, and not knowing where to begin. Our tendency to exclude people is fostered by a number of normal perceptual tendencies: 1. Social categorization. Our tendency to group and classify objects, including social categories, is ordinarily innocuous, facilitating acquisition of information and memory (Tajfel & Wilkes, 1963). Social categorizations can become invidious, however, when they serve as a basis for rationalizing structural inequality and social injustice. For example, race is a neutral physical characteristic, but it often becomes a value-loaded label, which generates unequal treatment and outcomes (Archer, 1985; Tajfel, 1978). 2. Evaluative judgments. Our tendency to make simple, evaluative, dichotomous judgments (e.g., good and bad, like and dislike) is a fundamental feature of human perception. Evaluative judgments have cognitive, affective, and moral components.

#### Debaters shouldn’t have to prove oppression is bad.

Alston & Timmons 14, Jonathan Alston and Aaron Timmons, 4-28-2014, “Nobody Knows the Trouble I See” (And In National Circuit Lincoln-Douglas Debate, Does Anyone Really Care?), https://www.vbriefly.com/2014/04/28/20144nobody-knows-the-trouble-i-see-and-in-national-circuit-lincoln-douglas-debate-does-anyone-really-care/, 8-10-2021

Above are statements that we and our students have heard from judges. There are many other equally offensive statements that can be shared. It seems like the statements above, and similar comments, have become more frequent. Recently the National Symposium on Debate featured a strategy article by Emily Massey, Geoffrey Kristoff and Grant Reiter that inadvertently—I do not believe that they fully understand the implication of their words—perpetuates the hateful and hostile atmosphere that exists in high school Lincoln-Douglas debate. Hundreds of students around the country are coached to say that oppression, rape, genocide, and lynching are not inherently bad. “You have to explain why they’re bad,” say many respected leaders in the community. Instead of engaging in a debate about the best methods to prevent, reduce, mitigate, eradicate oppression, too many adults, coaches, and judges in high school Lincoln-Douglas debate believe a more “strategic” conversation is to talk about the philosophy that justifies why such things are bad. But doesn’t having to prove rape is bad open up the possibility that it is not?

#### This means you should vote affirmative in this debate if I prove that reducing intellectual property minimizes oppression.

### Contention 1 – Vaccine Imperialism

#### Current intellectual property law exacerbates inequalities between countries in the Global North and South. This has empirically resulted in disparate life outcomes.

Vanni 21 – Dr. Amaka Vanni is Lecturer in Law at the University of Leeds. ("On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism," 3-23-2021, <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>

While the response to COVID-19 has shown what can be accomplished when the world works together, it has also underscored three interrelated points. First, the neoliberal framework – including the critical role intellectual property (IP) law plays in constituting this form of civilisation – is an unsuitable model for delivering the goods needed to respond to global health emergencies. The current economic/market system does not allow for equitable responses to infectious diseases, particularly access to sufficient medical and health resources. This inequity was obvious in the early days of the pandemic when test kits, PPEs, and ventilation machines were being distributed on the basis of who could pay the most rather than who needed them the most. Second, the beggar-thy-neighbor response currently adopted by developed countries hurts everyone because failing to stop the spread of the virus globally allows more mutations, which makes existing vaccines less effective. As COVID-19 has shown, no one is safe until everyone is safe. Yet, despite this warning, the hoarding of vaccines by developed countries continues unabated and speaks to the wider racist capitalist system we live in. If anything, this crude accumulation of vaccines reinforces North-South economic and political dominance and marks, as Onur Ince observes, the conceptual locus of political violence operative in the global genealogy of capitalism.

Third, while COVID-19 may endanger us all, it is far more costly to some than others. Numerous reports have shown how black and brown people are most impacted by the pandemic. In the United States, for example, indigenous Americans have the highest COVID-19 mortality rates nationwide while African American communities have COVID-19 mortality that is 2.3 times higher than the rate for Asians and Latinxs, and 2.6 times higher than the rate for Whites. Similar data is also emerging in the UK where people from black and minority ethnic groups are at greater risk of dying from coronavirus. This means those groups suffer higher loss of life compared to other racial groups due to inequities in healthcare access as well as higher rate of pre-existing conditions. In other parts of the world, the most vulnerable and the economically marginalized such as those working in the informal sector and living in shanty towns are feeling the effects of the pandemic the most. In Latin America and the Caribbean, 70 per cent of domestic workers have been affected by the pandemic where most have stopped receiving income. In Ghana, residents of slums at Old Fadama – a suburb in Accra – were made homeless when the government demolished their homes. The ensuing homelessness means there is little to no space of observing social distancing rules, access to running water and access to other resources to practice basic hygiene. Meanwhile in India, the pandemic has unsurprisingly hit the country along caste lines where the Dalits are most impacted because many are poor and have limited access to healthcare.

As Kimberlé Williams Crenshaw reminds us, the high number of minority deaths is not new. Rather, this crisis simply amplified racism and other forms of structural inequality as a pre-existing condition – an intersectional issue – where those disproportionately hurt are those who are already structurally marginalized. Thus, while recognising a broken global IP regime that triggered the scramble for vaccines, the racialized impact of the pandemic cannot be ignored, and it points to the entangled roots of race and capitalism.

The rest of this analysis takes a close look at some of the legal, political and economic forces that have animated IP rights and access to COVID-19 vaccine. It will focus on how the entanglement of corporate capture of global IP regime, state complicity and vaccine imperialism have come together to shape public health responses to the pandemic. It underscores how the law, in this case international IP law, consistently shelters capital and operates as an expression to further corporate pharmaceutical interests. If there is a lesson to be gleaned from this pandemic, it is that intellectual property is not failing us but is functioning the way it is set up to do. As the history of IP globalization has shown, the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is a transplant of the Euro-American model of property, driven by multinational corporations who used their respective national governments to underwrite and export their domestic IP claims. Therefore, it is unsurprising that this international legal regime employed to advance the interests of particular classes, nations and regions at the expense of others continues to reproduce extreme inequality with human costs.

#### The current intellectual property regime is at the heart of that imbalance. Property standards allocate wealth towards the privileged class who have access to medicine, and systematically exclude developing countries. Furthermore, intellectual property inflates the price of live-saving medicines which are critical to mitigate the effects of public health emergencies like COVID.

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Intellectual property rights (IPRs) are time-limited legal rights granted to inventors and creators. IPRs include copyrights, trademarks, patents, trade secrets, and geographical indications, while protected subject-matters include, but are not limited to, brands, inventions, designs, and biological materials. Importantly, IPRs overlap as a product may be covered by a series of rights. For example, a pharmaceutical medicine, defined by Britannica as a ‘substance used in the diagnosis, treatment, or prevention of disease’, is protected by patents, trademarks, and trade secrets. Patents are the most common form of IPR used for the protection of innovation in pharmaceuticals. Patents grant inventors limited market exclusivity for their inventions, and, in exchange, the inventor must disclose sufficient information such that competitors will be able to step into the market. This disclosure allows a competitor to make preparation to enter the market at the end of the monopoly period. Due to this legally-mandated exclusivity, patent owners – usually multinational corporations – have the right to prevent others from making, using, or selling a patented invention. The TRIPS Agreement, concluded as part of the Uruguay Round of multilateral trade negotiation and in force since 1995, provides a minimum of 20 years patent protection. The belief is that the duration allows corporations to recoup the expenses of developing, testing and upscaling an innovative pharmaceutical product.

From the onset, the TRIPS IP regime created imbalance between innovation, market monopoly, and medicines access, because it failed to take into consideration the health burden, development needs and local conditions of the various countries that make up the WTO. This has led to several issues. First, the market monopoly of IP rights, which allows the corporation to set the market for drugs, has created a privileged societal class with access to lifesaving medication distinguishing them from those excluded from access to available medications. This phenomenon is vividly illustrated in the HIV/AIDS crisis of the 1990s and early 2000s. While HIV/AIDS patients in developed countries were able to afford antiretroviral (ARVs) treatments, which had been developed, approved and patented as early as 1987, many patients in Africa and other parts of the developing world could not afford the approximately USD 12,000 per annum treatment at that time. By 2001, approximately 2.4 million people in the region had died of AIDS. The South African government intervened to reduce the cost of ARVs by amending its domestic patent laws to allow the authorization of parallel imports of patented pharmaceuticals and to encourage the use of generic drugs, but it was sued by the US industry group Pharmaceutical Research and Manufacturers of America (PhRMA). Though the lawsuit was eventually dropped, it highlights the measures pharmaceutical corporations, backed by some national governments, are willing to take to protect their profits at the cost of human lives. Significantly, we see how law (or the threat of legal action) is used not only to protect and expand the profitability of a certain kind of property but, as Anjali Vats and Deidré Keller have taught us, also reveals IP law’s racial investments in whiteness and its continuing implications for racial (in)equality, particularly in the way it informs systems of ownership, circulation, and distribution of knowledge. Similarly, Natsu Saito takes up the analysis of IP, race and capitalism by theorizing some of the ways in which ‘value’ in IP law concentrated in the hands of large corporations is calculated in terms of its profitability rather than what it contributes to the well-being of society. However, the proverbial chickens have come home to roost as even rich countries are beginning to feel the bite of the dysfunctional IP system.

The issue of excessive pricing for medicines is a growing problem in developed countries as well and has now become the single biggest category of healthcare spending in these states, particularly the US. An empirical report by I-MAK reveals how excessive pharmaceutical patenting is extending monopolies and driving up drug prices. The report, for example, notes that over half of the top twelve drugs in the US have more than 100 attempted patents per drug. Specifically, the report revealed that Humira® by AbbVie (used in the treatment of Crohn’s disease and the US’s highest grossing drug) has been issued 130 patents. The drug costs USD 44,000 annually and generated more than USD 19.2 billion for the company in 2019 alone. The Report also notes that the first patent filed for Herceptin® – used in the treatment for certain breast and stomach cancers – was in 1985 but currently has pending patent applications that could extend its market monopoly for 48 more years. Meanwhile, Celgene has over 105 patents for its oral cancer drug Revlimid® (used in the treatment of multiple myeloma) extending its monopoly until the end of 2036 – a patent lifespan of 40 years. In addition to excessive patenting and pricing, we have also come to understand the power of data in this context.

Second, regulatory agencies worldwide require drugs to undergo safety and efficacy testing to ensure they are harmless before approval. These tests, known as clinical trials, involve human subjects and are costly because they can run up to three separate phases. The data collected during these clinical trials are the proprietary materials of the company conducting the tests. Because it is expensive and time-consuming, generic drug companies usually rely on the safety and efficacy data of brand name companies to seek regulatory approval as long as they can prove their generic version is chemically and biologically equivalent to the original. Relying on the test data of brand name companies reduces the production cost for generic medicines and allows for quicker market entry. However, recent years have seen a promotion of time-limited, legally mandated protection against the non-proprietary use of such data by generic companies. This is known as data exclusivity. Put differently, data exclusivity is a period when a generic company cannot use the clinical trial data of an innovator pharmaceutical company to receive regulatory approval for a generic medicine. In so doing, data exclusivity provides a layer of protection in addition to patent protection to further delay market entry of generic medicines.

Data exclusivity periods vary depending on the jurisdiction. For example, it is twelve years in US and ten years in the EU. While the TRIPS Agreement does not create property rights over registration data, the US and the EU have continued to champion and export data exclusivity through free trade agreements, particularly for biologics. For example, the US Affordable Health Care for America Act in 2009 extended a 12-year exclusivity period for biologics. This US interpretation for registration data was also included in the United States-Mexico-Canada Agreement (USMCA), which sought a 10-year data exclusivity for new biologics. However, after intense negotiations, the data exclusivity protection was reduced to 5 years for new pharmaceuticals. In this instance, we see a crystallising of Euro-American ideas of property and a willingness to promote those property interests through the law, both domestic and international. In fact, certain scholars assert that this pursuit of higher TRIPS standards is driven, in part, by the US desire to achieve levels of protection it anticipated from the TRIPS Agreement but failed to secure. Given the influence of the industry and its representative group, PhRMA, in seeking stronger protection on a global scale, it is not surprising that the US’s post-TRIPS policies continue to rachet up standards in ways that undermine access to affordable medicines, and perpetuate social hierarchy and subordination.

Third, patent practices in recent decades have seen pharmaceutical companies engaging in trivial and cosmetic tweaking of a drug whilst still reaping the benefit of 20 years of patent protection. This tweaking sometimes involves making minor changes to patented drugs, such as changes in mode of administration, new dosages, extended release, or change in color of the drug. These changes normally do not offer any significant therapeutic advantage even though pharmaceutical companies argue they provide improved health outcomes to patients. These additional patents on small changes to existing drugs, known as evergreening or patent thickets, block the early entry of competitive, generic medicines that drive medicine prices down. For example, while not mandated by TRIPS, many US led TRIPS-plus free trade agreements have expanded the scope for evergreening. These include the US-Jordan FTA (2000), US-Australia FTA (2004) as well as the US-Korea FTA (2007), which allow for the patenting of new forms, uses, or methods of using existing products.

The cancer drug Gleevec®, owned by Novartis, is another example of how pharmaceutical companies often secure patents on new, more convenient versions with marginal therapeutic benefit to patients whilst blocking the entry of generic medicines. In 2013, Novartis’ patent application for Gleevec®– the β crystalline form of the salt imatinib mesylate – was rejected by the Indian Supreme Court because it lacked novelty. However, the company has secured patents for this product in other jurisdictions such as the US and has maintained a high price of Gleevec there. But in India the price of Gleevec® was reduced from approximately USD 2,200 to USD 88 for one month’s treatment in the generic drugs market as a result of the 2013 Indian Supreme Court judgement. Novartis is not the only culprit. The depression drug Effexor® by Pfizer was granted an evergreen patent when the company introduced an extended-release version, Efexor-XR®, even though there was no additional benefit to patients. Eventually, the patent was declared invalid, but by then it had already cost an estimated USD 209 million to Australian taxpayers and kept generic competition off the market for two and a half years. In another instance, Pfizer went on to secure an additional patent for the Pristiq®, which contained identical chemical compound as Efexor-XR®,and again with no added therapeutic benefit.

These evergreening practices, of course, have material effects. Apart from delaying the entry of generic versions, they give brand-name pharmaceutical companies free reign in the market, which allows them to set the market price. Recent years have seen monopoly prices rise exorbitantly causing significant financial strain to patients, domestic healthcare services and even insurance companies in developed countries. A notorious example is Martin Shkreli, who in 2015 bought the rights to an anti-malarial drug, then raised the price by 5,000 per cent from a cost of USD 13.50 to USD 750. Similarly, a white paper by I-MAK shows how excessive patenting and related strategies are driving families to overspend on lifesaving medicines. Celgene, the makers of Revlimid® raised the price of the drug by more than 50 per cent since 2012 to over USD 125,000 per year of treatment. Using the example of Solvadi® by Gilead, which costs USD 84,000 per treatment, Feldman notes the drug would cost the US Department of Defense more than USD 12 billion to treat all hepatitis-infected patients in US Veterans Affairs. But the US is not alone. In Europe, expensive drugs have prompted a growing backlash against pharmaceutical corporations. Reacting to these price hikes, Dutch pharmacies are bypassing these exorbitant prices by preparing medicines in-house for individual patients. The broken IP system ranging from an extraordinarily low standard for granting patents to permissions of patent thickets around a single molecule has not only severely distorted the system of innovation, but they have also skewed access to life-saving drugs. As a result, prices for new and existing medicines are constantly rising, making essential medicines inaccessible for millions of people around the world.

#### The affirmative is critical to combat vaccine imperialism – an IP reduction for medicines puts vaccines in the hands of the people who need it.

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Despite calls to make COVID-19 vaccines and related technologies a global public good, western pharmaceutical companies have declined to loosen or temporarily suspending IP protections and transfer technology to generic manufacturers. Such transfer would enable the scale-up of production and supply of lifesaving COVID-19 medical tools across the world. Furthermore, these countries are also blocking the TRIPS waiver proposal put forward by South Africa and India at the WTO despite being supported by 57 mostly developing countries. The waiver proposal seeks to temporarily postpone certain provisions of the TRIPS Agreement for treating, containing and preventing the coronavirus, but only until widespread vaccination and immunity are achieved. This means that countries will not be required to provide any form of IP protection on all COVID-19 related therapeutics, diagnostics and other technologies for the duration of the pandemic. It is important to reiterate the waiver proposal is time-limited and is different from TRIPS flexibilities, which are safeguards within the Agreement to mitigate the negative impact of patents such as high price of patented medicines. These safeguards include compulsory licenses and parallel importation. However, because of the onerous process of initiating these flexibilities as well as the threat of possible trade penalties by the US through the United States Trade Representative (USTR) “Special 301” Report targeting countries even in the absence of illegality, many developing countries are reluctant to invoke TRIPS flexibilities for public health purposes. For example, in the past, countries such as Colombia, India, Thailand and recently Malaysia have all featured in the Special 301 Report for using compulsory licenses to increase access to cancer medications. It is these challenges that the TRIPS waiver seeks to alleviate and, if approved, would also provide countries the space, without fear of retaliation from developed countries, to collaborate with competent developers in the R&D, manufacturing, scaling-up, and supply of COVID-19 tools. However, because this waiver is being opposed by a group of developed countries, we are grappling with the problem of artificially-created vaccine scarcity. The effect of this scarcity will further prolong and deepen the financial impact of this pandemic currently estimated to cost USD 9.2 trillion, half of which will be borne by advanced economies. Thus, in opposing the TRIPS waiver with the hopes of reaping huge financial rewards, developed countries are worsening pandemic woes in the long term.

Another kind of scarcity caused by vaccine nationalism has also reduced equitable access. Vaccine nationalism is a phenomenon where rich countries buy up global supply of vaccines through advance purchase agreements (APA) with pharmaceutical companies for their own populations at the expense of other countries. But perhaps it is time to reorient our sight and call the ongoing practices of buying up global supply of vaccine what it truly is – vaccine imperialism. If we take seriously the argument put forward by Antony Anghie on the colonial origins of international law, particularly how these origins create a set of structures that continually repeat themselves at various stages, we will begin to see COVID-19 vaccine accumulation not only as political, but also as imperial continuities manifesting in the present. Take, for instance, the report released by the Duke Global Health Innovation Center that shows that high-income countries have already purchased nearly 3.8 billion COVID-19 vaccine doses. Specifically, the United States has secured 400 million doses of the Pfizer-BioNTech and Moderna vaccines, and has APAs for more than 1 billion doses from four other companies yet to secure US regulatory approval. The European Union has similarly negotiated nearly 2.3 billion doses under contract and is negotiating for about 300 million more. With these purchases, these countries will be able to vaccinate their populations twice over, while many developing states, especially in Africa, are left behind. In hoarding vaccines whilst protecting the IP interests of their pharmaceutical multinational corporations, the afterlife of imperialism is playing out in this pandemic.

Moreover, these bilateral deals are hampering initiatives such as the COVID-19 Vaccine Global Access Facility (COVAX) – a pooled procurement mechanism for COVID-19 vaccine – aimed at equitable and science-led global vaccine distribution. By engaging in bilateral deals, wealthy countries impede the possibility of effective mass-inoculation campaigns. While the usefulness of the COVAX initiative cannot be denied, it is not enough. It will cover only the most vulnerable 20 per cent of a country’s population, it is severely underfunded and there are lingering questions regarding the contractual obligations of pharmaceutical companies involved in the initiative. For instance, it is not clear whether the COVAX contract includes IP-related clauses such as sharing of technological know-how. Still, even with all its faults, without a global ramping-up of production, distribution and vaccination campaigns via COVAX, the world will not be able to combat the COVID-19 pandemic and its growing variants. Health inequity and inequalities in vaccine access are not unfortunate outcomes of the global IP regime; they are part of its central architecture. The system is functioning exactly as it is set up to do.

These events – the corporate capture of the global pharmaceutical IP regime, state complicity and vaccine imperialism – are not new. Recall Article 7 of TRIPS, which states that the objective of the Agreement is the ‘protection and enforcement of intellectual property rights [to] contribute to the promotion of technological innovation and to the transfer and dissemination of technology’. In similar vein, Article 66(2) of TRIPS further calls on developed countries to ‘provide incentives to enterprises and institutions within their territories to promote and encourage technology transfer to least-developed country’. While the language of ‘transfer of technology’ might seem beneficial or benign, in actuality it is not. As I discussed in my book, and as Carmen Gonzalez has also shown, when development objectives are incorporated into international legal instruments and institutions, they become embedded in structures that may constrain their transformative potential and reproduce North-South power imbalances. This is because these development objectives are circumscribed by capitalist imperialist structures, adapted to justify colonial practices and mobilized through racial differences. These structures are the essence of international law and its institutions even in the twenty-first century. They continue to animate broader socio-economic engagement with the global economy even in the present as well as in the legal and regulatory codes that support them. Thus, it is not surprising that even in current global health crisis, calls for this same transfer of technology in the form of a TRIPS waiver to scale up global vaccine production is being thwarted by the hegemony of developed states inevitably influenced by their respective pharmaceutical companies. The ‘emancipatory potential’ of TRIPS cannot be achieved if it was not created to be emancipatory in the first place. It also makes obvious the ways international IP law is not only unsuited to promote structural reform to enable the self-sufficiency and self-determination of the countries in the global south, but also produces asymmetries that perpetuate inequalities.

### Contention 2 – COVID in India

#### Today, India is in crisis – their infrastructure cannot solve for COVID without increased vaccination rates. Modi’s regime has been ineffective, reducing credibility and increasing case numbers.

New York Times 9/17 – What to Know About India’s Coronavirus Crisis, https://www.nytimes.com/article/india-coronavirus-cases-deaths.html,

A deadly second wave of [coronavirus](https://www.nytimes.com/2021/08/17/world/asia/india-covid-19.html) infections is devastating [India](https://www.nytimes.com/2021/08/17/world/asia/india-covid-19.html), leaving millions of people infected and putting stress on the country’s already overtaxed health care system. Officially, by late May, about 27 million infections had been confirmed and more than 300,000 people were dead, but experts said the [actual figures were most likely much higher](https://www.nytimes.com/interactive/2021/05/25/world/asia/india-covid-death-estimates.html). At one point, India had been responsible for more than half of the world’s daily [Covid-19](https://www.nytimes.com/2021/08/31/business/economy/india-economy-covid.html) cases and set a record-breaking pace of about 400,000 a day.The official numbers show signs of easing. The major cities of Delhi and Mumbai, hit hard at the beginning of the second wave, have reported sharp drops in new infections and deaths. [On May 31, Delhi lifted restrictions on manufacturing and construction](https://www.nytimes.com/2021/05/31/world/asia/india-covid.html), critical drivers of an economy that has been battered by the pandemic. But life in the capital city is not expected to return to normal immediately. Schools and most businesses are still closed.Still, the virus is likely spreading through [the rest of the country](https://www.nytimes.com/2021/05/11/world/asia/covid-india-ganges-oxygen.html), and only a tiny portion of the population [has been fully vaccinated](https://www.nytimes.com/2021/05/06/world/asia/india-covid-vaccines.html). For the most up-to-date figures, The New York Times [is tracking the latest case counts here.](https://www.nytimes.com/interactive/2020/world/asia/india-coronavirus-cases.html) Some in India blame a new variant.Months ago, India appeared to be weathering the pandemic. After a harsh initial lockdown, the country did not see an explosion in new cases and deaths comparable to those in other countries.But after the early restrictions were lifted, many Indians stopped taking precautions. Large gatherings, [including political rallies and religious festivals](https://www.nytimes.com/2021/04/09/world/asia/india-covid-vaccine-variant.html?action=click&module=RelatedLinks&pgtype=Article), resumed and drew millions of people. Beginning this spring, the country recorded an exponential jump in cases and deaths.By April, some vaccinated individuals, including 37 doctors at one New Delhi hospital, were found to have contracted the virus, leaving many to wonder if a more contagious variant was behind the second wave.Many in India already assume that the [variant, B.1.617](https://www.nytimes.com/2021/05/14/world/uk-covid-india.html), is responsible for the severity of the second wave. The variant is sometimes called “the double mutant,” though the name is a misnomer because it has many more mutations than two. It garnered the name because one version contains two genetic mutations found in other difficult-to-control variants.Researchers outside of India say the limited data so far suggests instead that the variant called B.1.1.7, which [has affected Britain and the United States](https://www.nytimes.com/2021/04/07/us/politics/coronavirus-variants-cdc.html), is more likely to blame.The World Health Organization has called B.1.617.2 [“a variant of concern”](https://www.nytimes.com/2021/05/10/world/asia/india-covid-virus-variant.html) and said preliminary studies suggested an increased rate of transmission. That research, however, is limited and has not yet been peer reviewed, and scientists caution that other factors could explain the viciousness of the outbreak.Whatever the outcome, the variant is [now spreading in Britain](https://www.nytimes.com/2021/05/24/world/europe/india-uk-variant-vaccine-coronavirus.html), Nepal and other places. Scientists say that the vaccines currently available appear to be effective against it.Critics cite the Modi government’s policies for worsening the crisis.At the center of the India’s crisis is Prime Minister Narendra Modi, who early this year declared victory over the virus.Mr. Modi’s Covid-19 task force did not meet for months. His health minister assured the public in March that India had reached [the pandemic’s “endgame.”](https://pib.gov.in/PressReleasePage.aspx?PRID=1703017) As infections rose, Mr. Modi allowed large gatherings to help his governing Bharatiya Janata Party and burnish its Hindu nationalist credentials. His government approved a Hindu festival with millions of worshipers. He campaigned in state elections without a mask at rallies of thousands of maskless supporters. Critics say his administration was determined to cast an image of India as back on track and open for business despite lingering risks. At one point, officials dismissed warnings by scientists that India’s population remained vulnerable and had not achieved “herd immunity” as some in his administration were suggesting.In an editorial, The Lancet, a medical journal, [wrote](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01052-7/fulltext) that Mr. Modi “seemed more intent on [removing criticism” on social media](https://www.nytimes.com/2021/04/25/business/india-covid19-twitter-facebook.html) than “trying to control the pandemic.” The Indian Medical Association has called for a “complete, well-planned, pre-announced” lockdown.The growing distress across the country has tarnished Mr. Modi’s aura of political invulnerability, which he won by steamrolling the opposition and by leveraging his personal charisma to become India’s most powerful politician in decades. Opposition leaders are on the attack, and his central hold on power has increasingly made him the target of scathing criticism online. In early May, in the first local elections since the start of the second wave, Mr. Modi’s B.J.P. was unable to secure a much-sought-after victory[in West Bengal](https://www.nytimes.com/2021/05/02/world/asia/india-west-bengal-elections-modi.html?searchResultPosition=1), one of India’s most populous states. The B.J.P. won more seats in the local legislature than it did in the last election, but was unable to seize control from the opposition All India Trinamool Congress, an indication of displeasure at Mr. Modi’s handling of the Covid crisis. Government Responsibility[Prime Minister Modi’s](https://www.nytimes.com/2021/05/01/world/asia/india-covid19-modi.html?action=click&module=RelatedLinks&pgtype=Article) critics say that overconfidence and missteps have tarnished his image of invincibility. A shortage of oxygen and hospital beds leaves patients scrambling.Overwhelmed by new cases, Indian hospitals cannot cope with the demand, and patients in many cities have been abandoned to die. Clinics across the country have reported an acute shortage of hospital beds, medicines, protective equipment and oxygen. The Indian government [says that it has enough liquid oxygen](https://indianexpress.com/article/india/coronavirus-second-wave-oxygen-crisis-more-than-supply-lack-of-tankers-and-plant-location-key-challenges-7291716/) to meet medical needs and that it is rapidly expanding its supply. But production facilities are concentrated in eastern India, far from the worst outbreaks in Delhi and in the western state of Maharashtra, and it can take several days for supplies to reach there by road.Families of the sick are filling social media with pleas for oxygen as supplies run low at hospitals or because they are trying to administer care at home. Fraudsters and black marketeers [have emerged](https://www.nytimes.com/2021/05/16/world/asia/india-covid19-black-market.html). Oxygen and beds have become increasingly available in Delhi as new infections have dropped. Still, dire needs remain in other parts of the country.India makes vaccines for the world, but few Indians have been inoculated. India is one of the world’s leading vaccine manufacturers, but it has struggled to inoculate its citizens. New inoculations have fallen as supplies have tightened, leading to temporary closures of vaccination centers in Delhi and some other places. Only about 3 percent of the population has been fully vaccinated. Now, the country’s pain may be felt around the world, especially in poorer countries. India had planned to ship out millions of doses. But given its stark vaccination shortfall, [exports have essentially been shut down](https://www.nytimes.com/2021/03/25/world/asia/india-covid-vaccine-astrazeneca.html), leaving other nations with far fewer doses than they had expected.

#### Reducing IP rules is necessary to increase vaccine production – the affirmative increases timely access to vaccines.

Pandey 21 – (Ashutosh Pandey) “Rich countries block India, South Africa's bid to ban COVID vaccine patents,” DW, April 2, 2021. <https://www.dw.com/en/rich-countries-block-india-south-africas-bid-to-ban-covid-vaccine-patents/a-56460175>

The World Trade Organization (WTO) talks on a proposal by India and South Africa to temporarily suspend intellectual property (IP) rules related to COVID-19 vaccines and treatments hit a roadblock on Thursday after wealthy countries balked at the idea, Germany's dpa news agency reported. The two developing countries say the IP waiver will allow drugmakers in poor countries to start production of effective vaccines sooner. India and South Africa had approached the global trade body in October, calling on it to waive parts of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The suspension of rights such as patents, industrial designs, copyright and protection of undisclosed information would ensure "**timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID**-19," they said. The proposal was vehemently opposed by wealthy nations like the US and Britain as well as the European Union, who said that a ban would stifle innovation at pharmaceutical companies by robbing them of the incentive to make huge investments in research and development. This would be especially counterproductive during the current pandemic which needs the drugmakers to remain on their toes to deal with a mutating virus, they argue. The WTO talks are taking place as some wealthy countries face criticism for **cornering billions** of COVID shots — many times the size of their populations — while **leaving poor countries** struggling for supplies. **Experts say the global scramble for vaccines, or vaccine nationalism, risks prolonging the pandemic.** "We have to recognize that this virus knows no boundaries, it travels around the globe and the response to it should also be global. It should be based on international solidarity," said Ellen 't Hoen, the director of Medicines Law & Policy — a nonprofit campaigning for greater access to medicines. "Many of the large-scale vaccine manufacturers are based in developing countries. All the production capacity that **exists should be exploited**…and that does require the sharing of Not enough production capacity Supporters of the waiver, which include dozens of developing and least-developed countries and NGOs, said the WTO's IP rules were acting as a **barrier to urgent scale-up of production of vaccines** and other much needed medical equipment in poor countries.

#### Only a definitive reduction in IP rights can increase covid access – inequalities heighten the risk of mutations and uneven development.

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According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11

Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14

This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution.

TRIPS: Barrier to Equitable Health Care Access

The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16

Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19

A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21

The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding.

Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines.

One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer.

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally.

India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing.

Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

India’s Role in Ensuring Vaccine Equity India's response to COVID-19 at the global level was primarily two-fold. First, its proactive engagements in the regional and international platforms. Second, its policies and programmes to provide therapeutics and vaccines to the world. Since the beginning of the COVID-19 pandemic, India has been advocating international cooperation and policy coordination in fighting it. For instance, in April 2020, India co-sponsored a UN resolution that called for fair and equitable access to essential medical supplies and future vaccines to COVID-19. Later, in October 2020, India also put pressure on developed countries with a joint WTO proposal for TRIPS waiver. India’s Vaccine Maitri initiative also aims vaccine equity. As of 29 May 2021, India has supplied 663.698 lakh doses of COVID-19 vaccines to 95 countries. It includes 107.15 lakh doses as a gift to more than 45 countries, 357.92 lakh doses by commercial sales, and 198.628 lakh doses to the COVAX facility.29 The COVAX initiative aims to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of their income level. India has decided to supply 10 million doses of the vaccine to Africa and one million to the UN health workers under the COVAX facility. India has also removed the IPR of Covaxin that would help platforms like C-TAP once WHO and developed countries’ regulatory bodies approve the vaccine. If agreed, the waiver would benefit India in many ways. First, more vaccines will help the country to control the pandemic and its recurring waves. Second, it will be a boost to India's pharma industry, particularly the generic medicine industry. According to the Biotechnology Innovation Organization, 834 unique active compounds are involved in the current R&D of COVID-19 therapeutics, vaccines, and diagnostics. It means that thousands of new patents are awaited, and that will hinder India's ability to produce COVID-19 related medical products. Only through a waiver, this challenge can be addressed. Similarly, scientists note that mRNA is the future of vaccine technology. However, manufacturing mRNA vaccines involves complex processes and procedures. Only a very few Indian manufacturers have access to this technology; however, that too is limited. Once Indian companies have access to mRNA technology, it will help country’s generic medicine industry and boost India’s economy. Therefore, even if the WTO agrees on a waiver for a period shorter than proposed, India should accept it. In addition, mRNA vaccines can be produced in lesser time compared to the traditional vaccines. While traditional vaccines’ production takes four to five months, mRNA needs only six to eight weeks. Access to this technology will be vital for India in expediting the fight against COVID-19 and future pandemics. Finally, a waiver may strengthen India's diplomatic soft power. At present, what hinders India's Vaccine Maitri initiative is the scarcity of vaccines at home. On the other hand, China is increasing its standing in Africa, South America and the Pacific through vaccine diplomacy. The WHO approval of the Chinese vaccines and lack of access to vaccines by most developing countries, opens up huge space for China to do its vaccine diplomacy. Here, India should convince its Quad partners, particularly Australia and Japan, who oppose the waiver that vaccine production in developing countries through TRIPS waiver will enable the grouping to deliver its pledged billion doses of COVID-19 vaccine in the Indo-Pacific region. In short, the proposed waiver, if agreed, will help India in addressing the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.