



## Framework

I value morality, because the verb “ought” implies a moral obligation.

My criterion is utilitarianism.

Only utilitarianism can legitimately justify policies to the public, since they inevitably entail trade-offs. Though perhaps appropriate for individuals, rule-based moral codes create irresolvable bureaucracy when applied to governments.

Gary Woller [BYU Prof., “An Overview by Gary Woller”, A Forum on the Role of Environmental Ethics, June 1997, pg. 10]

Moreover, virtually all public policies entail some redistribution of economic or political resources, such that one group's gains must come at another group's expense. Consequently, public policies in a democracy must be justified to the public, and especially to those who pay the costs of those policies. Such justification cannot simply be assumed a priori by invoking some higher-order moral principle. Appeals to a priori principles, such as environmental preservation, also often fail to acknowledge that public policies inevitably entail trade-offs among competing values. Thus since policymakers cannot justify inherent value conflicts to the public, in any philosophical sense, and since public policies inherently imply winners and losers, the policymakers' duty to the public interest requires them to demonstrate that the redistributive effects and value trade-offs implied by their policies are somehow to the advantage of society. At the same time, deontologically based ethical systems have severe practical limitations as a basis for public policy. At best, a priori principles provide only general guidance to ethical dilemmas in public affairs and do not themselves suggest appropriate public policies, and at worst, they create a regimen of regulatory unreasonableness while failing to adequately address the problem or actually making it worse. For example, a moral obligation to preserve the environment by no means implies the best way, or any way for that matter, to do so, just as there is no a priori reason to believe that any policy that claims to preserve the environment will actually do so. Any number of policies might work, and others, although seemingly consistent with the moral principle, will fail utterly. That deontological principles are an inadequate basis for environmental policy is evident in the rather significant irony that most forms of deontologically based environmental laws and regulations tend to be implemented in a very utilitarian manner by street-level enforcement officials. Moreover, ignoring the relevant costs and benefits of environmental policy and their attendant incentive structures can, as alluded to above, actually work at cross purposes to environmental preservation. (There exists an extensive literature on this aspect of regulatory enforcement and the often perverse outcomes of regulatory policy. See, for example, Ackerman, 1981; Barrip and Fenn, 1983; Hawkins, 1983, 1984; Hawkins and Thomas, 1984.) Even the most die-hard preservationist/deontologist would, I believe, be troubled by this outcome. The above points are perhaps best expressed by Richard Flathman. The number of values typically involved in public policy decisions, the broad categories which must be employed and above all, the scope and complexity of the consequences to be anticipated militate against reasoning so conclusively that they generate an imperative to institute a specific policy. It is seldom the case that only one policy will meet the criteria of the public interest (1958, p. 12). It therefore follows that in a democracy, policymakers have an ethical duty to establish a plausible link between policy alternatives and the problems they address, and the public must be reasonably assured that a policy will actually do something about an existing problem; this requires the means-end language and methodology of utilitarian ethics. Good intentions, lofty rhetoric, and moral piety are an insufficient though perhaps at times a necessary, basis for public policy in a democracy.

Prefer utilitarianism for two additional reasons.

First, the government derives its legitimacy from a social contract, in which individuals give up freedom in exchange for protection from harm. Therefore, a government that doesn't look after its citizens' well-being would be illegitimate.

Second, death is the greatest denial of freedom since it destroys all possibilities and life projects – this means that life is the greatest impact under utilitarianism and relevant under any other ethical framework.

Bauman 95 [Zygmunt Bauman (University of Leeds Professor Emeritus of Sociology). “Life In Fragments: Essays In Postmodern Morality.” p. 66-71. 1995]

The being for is like living towards the future: a being filled with anticipation, a being aware of the abyss between future foretold and future that will eventually be; it is this gap which, like a magnet, draws the self towards the Other, as it draws life towards the future, making life into an

activity of overcoming, transcending, leaving behind. The self stretches towards the Other, as **life stretches towards the future**; neither can grasp what it stretches toward, but **it is in this hopeful** and desperate, never conclusive and never abandoned **stretching** toward **that the self is ever** anew **created and life ever** anew **lived**. In the words of M. M. Bakhtin, it is only in this not yet accomplished world of anticipation and trial, leaning toward stubbornly an other Other, that life can be lived not in the world of the 'events that occurred'; in the latter world, 'it is impossible to live, to act responsibly; in it, I am not needed, in principle I am not there at all.' Art, the Other, the future: what unites them, what makes them into three words vainly trying to grasp the same mystery, is the modality of possibility. A curious modality, at home neither in ontology nor epistemology; itself, like that which it tries to catch in its net, 'always outside', forever 'otherwise than being'. The possibility we are talking about here is not the all too familiar unsure of itself, and through that uncertainty flawed, inferior and incomplete being, disdainfully dismissed by triumphant existence as 'mere possibility', 'just a possibility'; possibility is instead 'plus que la reahte' both the origin and the foundation of being. The hope, says Blanchot, proclaims the possibility of that which evades the possible; 'in its limit, this is the hope of the bond recaptured where it is now lost.'" The hope is always the hope of being fulfilled, but what keeps the hope alive and so keeps the being open and on the move is precisely its unfulfilment. One may say that the paradox of hope (and the paradox of possibility founded in hope) is that it may pursue its destination solely through betraying its nature; the most exuberant of energies expends itself in the urge towards rest. Possibility uses up its openness in search of closure. Its image of the better being is its own impoverishment . . . The togetherness of the being for is cut out of the same block; it shares in the paradoxical lot of all possibility. It lasts as long as it is unfulfilled, yet it uses itself up in never ending effort of fulfilment, of recapturing the bond, making it tight and immune to all future temptations. In an important, perhaps decisive sense, it is selfdestructive and self defeating: its triumph is its death. The Other, like restless and unpredictable art, like the future itself, is a mystery. And being for the Other, going towards the Other through the twisted and rocky gorge of affection, brings that mystery into view makes it into a challenge. That mystery is what has triggered the sentiment in the first place but cracking that mystery is what the resulting movement is about. The mystery must be unpacked so that the being for may focus on the Other: one needs to know what to focus on. (The 'demand' is unspoken, the responsibility undertaken is unconditional; it is up to him or her who follows the demand and takes up the responsibility to decide what the following of that demand and carrying out of that responsibility means in practical terms.) Mystery noted Max Frisch (and the Other is a mystery), is an exciting puzzle, but one tends to get tired of that excitement. 'And so one creates for oneself an image. This is a loveless act, the betrayal.' Creating an image of the Other leads to the substitution of the image for the Other; the Other is now fixed soothingly and comfortably. There is nothing to be excited about anymore. I know what the Other needs, I know where my responsibility starts and ends. Whatever the Other may now do will be taken down and used against him. What used to be received as an exciting surprise now looks more like perversion; what used to be adored as exhilarating creativity now feels like wicked levity. Thanatos has taken over from Eros, and the excitement of the ungraspable turned into the dullness and tedium of the grasped. But, as Gyorgy Lukacs observed, 'everything one person may know about another is only expectation, only potentiality, only wish or fear, acquiring reality only as a result of what happens later, and this reality, too, dissolves straightaway into potentialities'. **Only death, with its finality and irreversibility, puts an end to** the musical chairs game of **the real and the potential** it

once and for all closes the embrace of togetherness which was before invitingly open and tempted the lonely self." 'Creating an image' is the dress rehearsal of that death. But creating an image is the inner urge, the constant temptation, the must of all affection . . . It is the loneliness of being abandoned to an unresolvable ambivalence and an unanchored and formless sentiment which sets in motion the togetherness of being for. But what loneliness seeks in togetherness is an end to its present condition an end to itself. Without knowing without being capable of knowing that the hope to replace the vexing loneliness with togetherness is founded solely on its own unfulfilment, and that once loneliness is no more, the togetherness ( the being for togetherness) must also collapse, as it cannot survive its own completion. What the loneliness seeks in togetherness (suicidally for its own cravings) is the foreclosing and pre emptying of the future, cancelling the future before it comes, robbing it of mystery but also of the possibility with which it is pregnant. Unknowingly yet necessarily, it seeks it all to its own detriment, since the success (if there is a success) may only bring it back to where it started and to the condition which prompted it to start on the journey in the first place. The togetherness of being for is always in the future, and nowhere else. It is no more once the self proclaims: 'I have arrived', 'I have done it', 'I fulfilled my duty.' The being for starts from the realization of the bottomlessness of the task, and ends with the declaration that the infinity has been exhausted. This is the tragedy of being for the reason why it cannot but be death bound while simultaneously remaining an undying attraction. In this tragedy, there are many happy moments, but no happy end. Death is always the foreclosure of possibilities, and it comes eventually in its own time, even if not brought forward by the impatience of love. The catch is to direct the affection to staving off the end, and to do this against the affection's nature. What follows is that, if moral relationship is grounded in the being-for togetherness (as it is), then it can exist as a project, and guide the self's conduct only as long as its nature of a project (a not yet-completed project) is not denied. Morality, like the future itself, is forever not yet. (And this is why the ethical code, any ethical code, the more so the more perfect it is by its own standards, supports morality the way the rope supports the hanged man.) It is because of our loneliness that we crave togetherness. It is because of our loneliness that we open up to the Other and allow the Other to open up to us. It is because of our loneliness (which is only belied, not overcome, by the hubbub of the being with) that we turn into moral selves. And it is only through allowing the togetherness its possibilities which only the future can disclose that we stand a chance of acting morally, and sometimes even of being good, in the present.

## Contention – Pandemic Response

### **Status quo TRIPS agreements provide insufficient flexibility for developing countries to combat the pandemic**

**Ranjan '21:** Prabhash Ranjan is Senior Assistant Professor at the Faculty of Legal Studies, South Asian University, New Delhi. “The Case for Waiving Intellectual Property Protection for COVID-19 vaccines.” Observer Research Foundation. April 6<sup>th</sup>, 2021.

<https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/>. FD.

**Those who oppose** India and South Africa’s **proposal for a TRIPS waiver argue that since the TRIPS Agreement contains several flexibilities that can be used to address public health**

**exigencies, the demand to suspend IP obligations is superfluous.**[37] Indeed, the TRIPS Agreement contains those flexibilities. One such important flexibility is compulsory license – the right of a government to issue a license to make use of a patent during the patent term without the patent holder’s consent, which is regulated by Article 31 of the TRIPS Agreement. Under Article 31, public non-commercial use is also possible—i.e. a government can authorise the use of a patent for its purposes.

According to a study, out of 144 instances of the use of TRIPS flexibility measures by 89 countries from 2001-2016, 100 instances were of compulsory licensing or public non-commercial use to increase the production of generic medicines at affordable prices.[38] Likewise, the study also found that a large number of LDCs made use of the long transition period available to them to comply with

the TRIPS Agreement[39] – another important TRIPS flexibility.[40] **It would be erroneous to conclude, however, that these flexibilities would be sufficient in dealing with all public health challenges especially one as massive as the current pandemic. The utility of the same TRIPS flexibility, such as compulsory license, is not the same for all countries.** While countries that have manufacturing ability in the pharmaceutical sector can effectively employ compulsory licenses, a large number of LDCs do not have such capability. **Even developing countries that can use compulsory licenses to produce patented drugs are always under pressure from developed countries not to issue**

**such licenses.** For example, India was subjected to relentless attacks by the US government when it issued a compulsory license in 2012 to produce a generic version of Bayer’s cancer drug.[41] As pointed out earlier, for countries that lack manufacturing ability, the compulsory license is not a useful flexibility. Article 31(f) of the TRIPS Agreement states that a compulsory license may be issued predominantly for the domestic market of the country issuing the license. **Thus, generic medicines produced under a compulsory license cannot be exported. As a result, countries that have limited manufacturing ability in the pharmaceutical sector will not be able to benefit from the provision on compulsory licensing given in Article 31 of the TRIPS Agreement.** This problem was recognised by the WTO in 2001 as evident

in paragraph 6 of the Doha declaration on TRIPS and Public Health. It states: “We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.” In August 2003, the WTO’s General Council adopted a decision that waived the obligations imposed by Articles 31(f) and 31(h) to allow countries to export drugs manufactured under compulsory licensing to countries that lacked the manufacturing ability.[42] Finally, in 2005, the TRIPS agreement was amended, which took effect on 23 January 2017,[43] to include Article 31 bis making the 2003 decision permanent. The fact that first the waiver followed by the amendment of the TRIPS Agreement was needed demonstrates that the TRIPS flexibilities were not adequate in addressing all the situations of drug scarcity. While this amendment has been touted as having solved the problem of countries with insufficient manufacturing ability to access drugs at affordable prices, concerns remain about the cumbersome process that countries need to follow to import and export such medicines.[44] For instance, if a country issues a compulsory license to export drugs to another nation that lacks manufacturing capability, the exporting country has to ensure that the drugs so manufactured are exported to that nation only; the medicines should be easily identifiable through different colour, or shape; only the amount necessary to meet the requirements of the eligible importing country are manufactured; and the importing country has to notify the WTO’s TRIPS council.[45] **These conditions disincentivise generic pharmaceutical manufacturers from manufacturing products under compulsory licenses for export.**[46] Since often, the countries that lack manufacturing capability are smaller in size, **there is less economies of scale to be reaped to attract the interest of generic**

**manufacturers to export drugs to such countries.**[47] Indeed, the problem with the economies of scale and the cumbersome procedure were evident in the only instance when this system was put to use in the last decade and a half, involving Rwanda and Canada.[48] In their proposal, India and South Africa identified the unworkable nature of Article 31 bis to address the challenges posed by Covid-19. Given that a large number of countries lack manufacturing capability in the pharmaceutical sector and that they would need Covid-19 vaccines for their population, the lengthy and cumbersome procedures listed in Article 31 bis would only hobble their efforts at universal inoculation. **Following the procedures listed in Article 31 bis for a large**

number of countries simultaneously would severely slow down the export of vaccines, thus proving to be costly when countries need these products urgently amid a pandemic. Therefore, the sheer scale of the problem and colossal demand for vaccines from all countries of the world make the TRIPS flexibility impracticable. There are other flexibilities as well such as voluntary licenses—i.e. licenses given by patent holders to generic companies on mutually agreed terms. The AstraZeneca Covid-19 vaccine, for instance, that has been licensed to India's Serum Institute is an example of a voluntary license. However, the voluntary licenses are often shrouded in secrecy where the patent holder controls important decisions such as who would be the ultimate beneficiaries of the drug and how the third-party sellers are to be selected. The same can be said about the voluntary license issued by AstraZeneca to Serum Institute.[49] To boost the production of vaccines to meet huge demand, several other companies would have to be upgraded, requiring a non-exclusive deal which is unlikely to happen.[50]

## **Prolonged lack of access to vaccines in developing countries magnifies the impact of COVID-19 – new variants and state collapse cause global instability and violence**

**Merelli 8-14-21:** Annalisa Merelli. “Low Vaccine Rates in Africa are a Global Security Issue”. Quartz Africa. August 14<sup>th</sup>, 2021.

<https://qz.com/africa/2047286/low-vaccination-rates-in-africa-can-cause-new-variants/>. FD.

More than 4.5 billion doses of Covid-19 vaccines have been administered across the world so far. Less than 200 million have gone to low-income countries. In rich countries, 44% of the population are fully vaccinated. Vulnerable individuals are about to get a third booster shot, and a majority of those who have yet to receive a vaccine have decided not to get one, despite having access to it. In poor countries, only 1% of the population received a single dose, and even fewer received both. This is dangerous for the whole world. Rich countries already have secured enough doses to cover their populations several times around. Recent commitments such as the billion doses promised to poor countries after the G7, or Canada's latest announcement of a 10 million dose donation, are steps in the right direction but continue to be insufficient. Further, the very plan of donating excess doses, no matter how many, exposes the inequity of the plan. It isn't about equitable global distribution, but about offering poor countries leftovers. But if the moral argument for better distribution has not sufficed, perhaps wealthy countries will listen to this: Leaving poor countries without vaccines represents a global security threat. We already know that in countries with low vaccination rates, especially where protective measures such as social distancing are hard to enforce, deadly new variants emerge. This happened in India, where the Delta variant emerged as outbreaks ravaged a country with low vaccination levels. The danger is even higher in low-income African countries, where it isn't just hard to come about vaccines, but even tests are scarce, so it's virtually impossible to even identify the size of outbreaks once they occur. Leaving billions unvaccinated will eventually reverberate all over the world, protracting the pandemic and making Covid-19 increasingly harder to control! That is, unless rich countries plan to completely isolate themselves from the rest of the world, says Mosoka Fallah, the former director-general of the National Public Health Institute of Liberia and a researcher in global health. There are cases of diseases, such as malaria or typhoid, that have vaccines or treatments in advanced economies yet continue to cause disease and even death in developing ones. But it's impossible to predict whether Covid-19 will develop in a similar way, becoming especially dangerous in certain areas and disappearing from others. “The unknowns are too many, and we don't know how this will end,” says Fallah. “The best way to predict the future is to look at the past, and we've seen Delta, we've seen what it's done.” The risk isn't just epidemiological either. “If Africa were to experience an outbreak of the level of India or Brazil, my worry is for state collapses,” says Fallah. The resources of most African nations aren't enough to sustain the social and economic shock of large Covid-19 outbreaks, and the risk of rough political actors taking advantage of the situation is very high. During the first stages of the pandemic, countries such as Uganda, Zimbabwe, or South Sudan have seen how easily lockdowns can be used as political tools to silence democratic debate, and more serious outbreaks can easily destabilize countries that have precarious healthcare systems and fragile economies. This, too, risks having consequences globally. Instability, together with the economic consequences

caused by the epidemic, would likely lead to displacement, causing refugee crises, and leaving people vulnerable to terrorism and other political manipulation.

## **Vaccine inequity is the single largest barrier to overcoming the COVID-19 pandemic**

**W.H.O '21:** World Health Organization. "Vaccine inequity undermining global economic recovery". July 22nd, 2021.

<https://www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery>. FD.

**COVID-19 vaccine inequity will have a lasting and profound impact on socio-economic recovery in low- and lower-middle income countries without urgent action to boost supply and assure equitable access for every country, including through dose sharing, according to new data released today by the United Nations Development Programme (UNDP), the World Health Organization (WHO) and the University of Oxford.**

An acceleration in scaling up manufacturing and sharing enough vaccine doses with low-income countries could have added \$38 billion to their GDP forecast for 2021 if they had similar vaccination rates as high income countries.

At a time when richer countries have paid trillions in stimulus to prop up flagging economies, **now is the moment to ensure vaccine doses are shared quickly, all barriers to increasing vaccine manufacturing are removed and financing support is secured so vaccines are distributed equitably and a truly global economic recovery can take place.**

A high price per COVID-19 vaccine dose relative to other vaccines and delivery costs – including for the health workforce surge – could put a huge strain on fragile health systems and undermine routine immunization and essential health services and could cause alarming spikes in measles, pneumonia and diarrhea. There is also a clear risk in terms of foregone opportunities for the expansion of other immunization services, for example the safe and effective rollout of HPV vaccines. Lower income countries need timely access to sustainably priced vaccines and timely financial support. These insights come from the Global Dashboard for COVID-19 Vaccine Equity, a joint initiative from UNDP, WHO and the University of Oxford's Blavatnik School of Government, which combines the latest information on COVID-19 vaccination with the most recent socio-economic data to illustrate why accelerating vaccine equity is not only critical to saving lives but also to driving a faster and fairer recovery from the pandemic with benefits for all.

**"In some low- and middle-income countries, less than 1 per cent of the population is vaccinated – this is contributing to a two-track recovery from the COVID-19**

**pandemic",** said UNDP Administrator, Achim Steiner. "It's time for swift, collective action – this new COVID-19 Vaccine Equity Dashboard will provide Governments, policymakers and international organisations with unique insights to accelerate the global delivery of vaccines and mitigate the devastating socio-economic impacts of the pandemic." According to the new Dashboard, which builds on data from multiple entities including the IMF, World Bank, UNICEF and Gavi, and analysis on per capita GDP growth rates from the World Economic Outlook, richer countries are projected to vaccinate quicker and recover economically quicker from COVID-19, while poorer countries haven't even been able to vaccinate their health workers and most at-risk population and may not achieve pre-COVID-19 levels of growth until 2024.

**Meanwhile, Delta and other variants are driving some countries to reinstate strict public health social measures. This is further worsening the social, economic and health impact, especially for the most vulnerable and marginalised people. Vaccine inequity threatens all countries and risks reversing hard won progress on the Sustainable Development Goals. "Vaccine inequity is the world's biggest obstacle to ending this pandemic and recovering from COVID-19,"** said Dr Tedros Adhanom Ghebreyesus, Director-General of the

**World Health Organization. "Economically, epidemiologically and morally, it is in all countries' best interest to use the latest available data to make lifesaving vaccines available to all."** Designed to empower policy makers and development partners to take urgent action to reduce vaccine inequity, the Global Dashboard breaks down the impact of accessibility against a target for countries to vaccinate their at-risk populations first to reduce mortality and protect the health system and then move on to vaccinating larger shares of the population to reduce disease burden and re-open socio-economic activity. The Dashboard is facilitated by the Global Action Plan for Healthy Lives and Well-being for All (SDG3 GAP), which aims to improve collaboration across the multilateral system to support an equitable and resilient recovery from the pandemic and drive progress towards the health-related SDGs.

**Plan: The member nations of the WTO ought to reduce IP protections for medicines pertaining to treatment of COVID-19. This entails a temporary**

## **waiver on IP protections for all materials necessary for prevention, treatment, or containment of COVID-19 – evidence clarifies**

**Thrasher '21:** Rachel Thrasher. “Why the TRIPS Waiver Should Include More than Just Vaccines”.

BU Global Development Policy Center. June 7<sup>th</sup>, 2021.

<https://www.bu.edu/gdp/2021/06/07/why-the-trips-waiver-should-include-more-than-just-vaccines/>. FD.

Nearly eight months after an initial proposal from India and South Africa, the United States surprised the world by making a public declaration of support for a Trade-Related Aspects of Intellectual Property (TRIPS) Waiver for COVID-19 vaccines at the World Trade Organization (WTO). Since then, proponents have been advocating for a waiver that is sufficiently broad in scope, coverage and duration to do the work of increasing equitable access to vaccines as well as other COVID-19 related products. Unfortunately, the waiver still does not appear to have the global support needed to get past the WTO practice of consensus-based decision-making. The focus from G7 countries on donating doses and funding COVAX continues to keep vaccine access to a conversation about how much of their slice of pie rich countries are willing to give away, rather than expanding the pie altogether. **And while the TRIPS Waiver is targeted at increasing vaccine production, the broader scope of the original proposal is cognizant of the complexity of this public health crisis by including other products that are crucial to the fight against the virus.** Arguments in favor of and against a TRIPS Waiver remain largely, and frustratingly, unchanged as the pandemic rages on. Opponents prioritize concerns that removing intellectual property protection during the pandemic will backfire and potentially make companies less likely to contribute to innovation during future pandemics. Supporters argue the COVID-19 pandemic is not the time to operate business-as-usual, where patents on tests, treatments and vaccines hinder access to critical products and put everyone at risk – “no one is safe until everyone is safe.” **WTO members should support a broad-scope TRIPS Waiver, applicable to a myriad of inventions and forms of intellectual property for two key reasons. First, millions more people are likely to contract COVID-19 and need treatment and care in the next few years, as the realities of vaccine production make it difficult to replicate in time to ramp up production in other countries quickly. Second, many products related to that treatment and care are potentially patent-protected, so a TRIPS Waiver could promote enhanced access to better care for sick people, even if the vaccines are not imminently available.** What exactly does the TRIPS Waiver say? The most recent version of the proposal put forth by the African Group, India and others, lays out a broad-based waiver of the rules governing IP rights listed in Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement, as well as the enforcement of those rules (Part III). This covers the protection of copyrights, industrial designs, patents and undisclosed information (e.g., trade secrets). The effect of such a waiver would be to allow countries to temporarily waive their domestic intellectual property laws which protect these types of knowledge and innovation. In countries where IP protection is waived, domestic producers could begin to manufacture and sell patent-protected products, for example, without negotiating a license with the originator firm, and without fearing domestic or international legal repercussions. **The waiver would also cover all “health products and technology...[for] the prevention, treatment or containment of COVID-19.” This includes diagnostics, therapeutic medicines, vaccines, devices, personal protective equipment and “all materials and components as well as methods and means of manufacture” of those products. The proposed waiver would be in place for three years with annual reviews by the WTO General Council and an additional review at the end of the three years to determine if the “exceptional circumstances” still apply and if the waiver should be extended.** Much less is known about the exact United States stance on the waiver text, except to note that public statements about the waiver have been limited to vaccines and their associated patents – making it less a bona fide TRIPS Waiver and more of a narrow vaccine patent waiver.

## **A TRIPS waiver is the key missing piece in resolving vaccine inequity – this answers CPs and the innovation DA**

**Ranjan '21:** Prabhash Ranjan is Senior Assistant Professor at the Faculty of Legal Studies, South Asian University, New Delhi. “The Case for Waiving Intellectual Property Protection for COVID-19 vaccines.” Observer Research Foundation. April 6<sup>th</sup>, 2021.

<https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/>. FD.

The global community began this year with the singular aim of ending the Covid-19 pandemic. This would only be possible if more and more people all over the world are vaccinated, and as quickly as possible. Given the enormous demand, the production of vaccines has to be increased manifold and followed by ensuring wider and equitable distribution. An IP waiver alone cannot accomplish such task. Increasing the production of vaccines and ensuring their equitable access would also require building the institutional capacity in several countries, overcoming systemic bottlenecks, and undertaking the necessary reforms in the administrative machinery and the legal framework. Nonetheless, a TRIPS waiver could be an important step in scaling up the production of the vaccines. Voluntary efforts like COVAX that aim to accelerate the development and production of vaccines might not be enough, given the enormity of the challenge. While countries that have manufacturing capability can make use of TRIPS flexibilities like compulsory licenses, the same cannot be said about those that lack such capacity especially LDCs in Africa and Asia. The argument that suspending IP rights would be a disincentive for the pharmaceutical sector is untenable; given the huge demand, these companies are assured of returns. Moreover, pharmaceutical companies often benefit from public grants and public money<sup>[51]</sup> including in the development of Covid-19 vaccines.<sup>[52]</sup> Therefore, it is legitimate that the benefits should be shared with the society at large. As the World Health Organization rightly says, “with a fast-moving pandemic, no one is safe, unless everyone is safe.”<sup>[53]</sup> Therefore, the global community needs to pull out all stops including a temporary TRIPS waiver.

## Human Rights

### Intellectual Property results in massive access gaps resulting in disproportionate health outcomes

Jung and Kwon 2015 ( Youn Jung and Soonman Kwon, The Effects of Intellectual Property Rights on Access to Medicines and Catastrophic Expenditure, *International Journal of Health Services*, vol. 45, no. 3, pp. 507–29. DOI.org (Crossref), doi:10.1177/0020731415584560)//NotJacob

Discussion This study investigated how the national level of IPR is associated with individuals' access to medicines and households' experience of catastrophic expenditure for medicines. **First, our results show that higher level of IPR is associated with low access to prescribed medicines. This adverse relationship between IPR and access to medicines is significant even after controlling for country income level and individuals' socioeconomic status and demographic characteristics. Adding other variables, which reflect the characteristics of each country's healthcare system, in the model did not change the significant effect of IPR on access to medicines, although the magnitude of the effect slightly decreased. These results imply that strengthened IPR for pharmaceuticals is functioning as a barrier to people's access to medicines. Even though each country's policy efforts, such as strengthening the infrastructure of healthcare provision and increasing the public expenditure for healthcare, have contributed to offsetting the negative impact of IPR on medicine utilization to some extent, the effect of IPR was still significant.** Our results also show that IPR exerts an influence on medicine utilization only in countries above a certain income level. We did not observe the significant effect of IPR on access to medicines in low-income countries where GDP per capita is below \$1000, whereas it was negatively associated with access to medicines in middle-income countries. These results are more likely to be related with access to healthcare, which is the premise of utilizing the prescription drugs. This study only included the population for whom medicines were prescribed when they visited health care providers, excluding the population who could not see healthcare providers even though they were in need. Given that a greater number of people are suffering from poor access to healthcare in low-income countries than in middle-income ones, no association between IPR and access to 524 International Journal of Health Services 45(3) medicines in low-income countries is more likely to be explained by this kind of sample selection problem. Furthermore, a gap between rules and practice in the enforcement of IPR may contribute to the non-significant impact of IPR in low-income countries. As Shadlen and colleagues pointed out,<sup>41</sup> low-income countries may have a large gap between rules and reality with regard to IPR, considering their limited resources for implementation and enforcement of IPR. The GP index that we used as an index of IPR in this study was developed by a text-based approach using the existing legal and institutional arrangements for patent systems, so it may not show us the full picture of actual protection level for IPR. Thus, we cannot exclude the possibility of this type of measurement error in low-income countries. We also found that those who live in rural areas have better access to medicines than those who live in urban areas. This may be related to sample selection process. Rural areas are likely to have inferior healthcare infrastructure, so rural residents have more difficulties in utilizing healthcare service. Because rural residents included in this study are those who visit healthcare providers despite this barrier, it is possible that they have more propensity to use healthcare, including prescribed medicines, than urban residents. This possibility is supported by the result that the coefficient of rural residence is bigger and significant in low-income countries, but not in middle-income countries, because the difference in healthcare infrastructure between rural and urban areas would be bigger in low-income countries than in middle-income ones. Next, our results show that the effects of the national healthcare system on access to medicines are not the same across countries with different income levels. **Although essential medicines lists and the number of doctors had positive significant relationships with access to medicines in low-income countries, only a public share of total**

**health expenditure had a significant impact in middleincome countries.** This suggests that the main types of access barrier that countries face are different according to their income level. Middle-income countries tend to suffer from nonaffordable price of medicines rather than availability problems, whereas low availability of essential medicines is a more serious issue for low-income countries. Last, our results show that IPR is not associated with households' catastrophic expenditure for medicines even though it is significantly associated with access to prescribed medicines. This is due to the possibility that many people cannot purchase medicines at all because of their poor purchasing capacity and the high price of medicines. As a result, they are likely to be excluded from the analysis.

**Accordingly, the results of this study provide strong empirical evidence for the linkage between IPR and access to medicines in developing countries. As we hypothesized, strengthening IPR led to lower access to medicines in developing countries, and particularly lower access for the poorest of the poor. This result Jung and Kwon 525 supports previous theoretical debate that patent protection may result in welfare loss in developing countries.6,18,42**

### IP imbalances create geographic disparities, only the affirmative solves!

Chen 2010 (Ge Chen, Fragmentation of International Law: the Impact on Access to Knowledge in International Copyright Law, World Intellectual Property organization)//NotJacob

Under the institutional lens, the redistributive value of knowledge goods is likewise relatively unheeded, though it has been embraced as GPG indispensable to the common progress of the human society.<sup>99</sup> In terms of neoclassical economics public goods are necessitated by the market failure to satisfy certain basic human needs which shall be in turn accommodated by government regulation in its policy of social welfare.<sup>100</sup> However, access rights in IP regimes have immanently covered up the complexity of the redistributive uncertainties entailed in the welfare disposition of knowledge goods.<sup>101</sup> In fact, how to ensure that the social benefits of recouping momentum for cumulative innovation from the current system are not diluted or offset by the social costs of deterring free riders with the relentless ratcheting up of IP standards constitutes a critical question which might otherwise adversely impinge on the provision and distribution of other public goods such as education and scientific research. In particular, when the imbalance is magnified on the global scale, the stakes will be considerably higher.<sup>102</sup> Presumably, by disentangling the unnecessarily fettered access to copyrighted works, the legislator could redefine the GPG and help the modern media like the Internet become an open marketplace for ideas and business transactions.<sup>103</sup> While ideas and information should then be used as a resource and management tool that allows the maximization of the value of processes and transactions,<sup>104</sup> an open market in the global trade sphere that distributes knowledge goods shall enable all nations including those with poor financial and innovative capacities to benefit from knowledge transfer.<sup>105</sup> It is the very vision of even distribution of sufficient GPG that has bolstered the uniform pursuit of optimal level of IP protection.<sup>106</sup> Unfortunately, however, the current paradigm of GPG governance fails to accommodate the needs of access to knowledge in developing countries due to the lack of a legitimate and effective regulatory regime that provides institutional backup to centralize and distribute all these global public resources on a uniform scale, which amounts to the “governance gap” on the international plane.<sup>107</sup> While developed countries have always treated knowledge in the form of creative expressions accomplished by their nationals as their exclusive natural resources worthy of strong legal protection,<sup>108</sup> knowledge cartels representing unilateral pursuit of private interests have manoeuvred into the centre of IP decision-making with their poignant lobbying capacities at the domestic level.<sup>109</sup> Moreover, these countries have endeavoured to exert great influence on global norm-setting in copyright fields and managed to impose a universally high standard comparable to their domestic level upon other nations as well.<sup>110</sup> In contrast, developing countries with limited innovation capacities and financial resources often claim that the benefits virtually accrue to consumers and users in other countries and postulate that divergent social and economic contingencies must be taken into consideration if global coordination in knowledge governance is to be made.<sup>111</sup>

The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by establishing health as a human right

Enshrining a Right to Health inside of Intellectual Property rights is not only legal, but necessary to change the institutionalization of medical accessibility!

Mike 2020 (Jennifer Mike, Access to essential medicines to guarantee women's rights to health: The pharmaceutical patents connection, <https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12161>, Jan 29 2020)//NotJacob

**All the aforementioned cases have one thing in common: the recognition that access to essential life-saving medicines is an important aspect of human rights, particularly life and health. Understanding the interpretation of access to medicines as a constituent of human rights leads to thinking about its centrality in the guarantee of all human rights.** Since access to medicines as a human right is dependent on several factors, including affordability, availability and an efficient healthcare system, it is argued that the state, particularly the government of developing countries have a duty to take proactive positive steps to strengthen their healthcare systems, prevent interference with the right to access medicines (including patent rights) and generally fulfil the obligation to provide affordable, safe and timely access to treatments for the practical enjoyment of human rights. Secondly, there is a legal obligation to ensure women's access to medication as a national legislative and policy priority which should be reflected in the health system and law including patent, competition, pricing, licensing and other relevant regulations. Thus, states are obliged to facilitate and enhance the means to accessing pharmaceuticals and drugs as a matter of human rights in their legislative and policy considerations. For example, since Article 8 of the TRIPS Agreement grants WTO members the flexible authority to "adopt necessary measures" compatible with the general provisions of the Agreement to safeguard public health and promote the interests of the public states can adapt their IP regimes to take into account the accessibility of its people to adequate medicines, as a human right. Also, the human right to access medicines can be recognised as legitimate grounds for the design and implementation of the exceptions to TRIPS' obligations and flexibilities regarding patents. Hestermeyer examines access to medicines as a human right within the framework of the WTO system and the TRIPS Agreement (2008, pp. 78–136). His study indicates that access to medicines as a human right is essential to the interpretation of the objective and purpose of the Agreement within the context of public health (2008, pp. 207–224). The study likewise illustrates that access to medicines as a right allows WTO members more discretion to take appropriate measures to guarantee accessibility (Hestermeyer, 2008, pp. 229–254). In 2013, the Intellectual Property Appellate Board (IPAB) of India considered whether compulsory licence can be granted to the applicant on the grounds that the drug was not "available to the public at a reasonable price" in accordance with Section 84(1)(b) of Indian Patents Act. The IPAB after a careful deliberation, dismissed the appeal filed by Bayer and confirmed the compulsory licence given to Natco (Bayer Corporation v Natco Pharma Ltd). The IPAB based its decision on the yardstick of the public in ruling that "[s]ection 84 [...] is only concerned with the price at which the drug is made to the public" (para 42). Significantly, the IPAB approached the appeal from the perspective of the public interest within the context of the right to life as guaranteed under Article 21 of the Constitution of India, 1950.<sup>54</sup> The ruling in this case upheld the primary importance of public health over private monopoly rights and gave impetus for the Indian Government to grant more compulsory licences in the interest of access to medicines. Similarly, the Indian Supreme Court in 2014, dismissed a petition by Bayer to set aside the compulsory license on the anticancer drug "Sorafenib Tosylate", otherwise

marketed as “Nexavar” (Spicy IP). The French authorities also considered the use of a compulsory licence for the pill Ru 486 and subsequently amended its laws to allow broader use of the ex officio licence for breast and ovarian cancer genetic diagnostic testing patents due to excessive prices and licensing restrictions (Correa, 2010, p. 598). **The impact of this decision is a big win for women as they can access the cheaper versions of the drugs, particularly improvised women.**