

Innovation DA

1NC Util Framework

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

My criterion is utilitarianism.

Tag

Citation

Text – body – evidence

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 moral 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 overall 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 moral 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; Bartrip 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 realite' 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.**

Climate Change DA

Patent waiver for Covid spills over—drives down innovation for climate research

Brand 2021 (Melissa Brand, TRIPS IP Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors, <https://www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/>)/Notjacob

“If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis, can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis?”

And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth?” While the discussions around waiving intellectual property (IP) rights set forth in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are currently (and somewhat amorously) limited to COVID-19 related drug and medical products, it is probably shortsighted to ignore the implications for other technologies critical to sustaining our environment and advancing a more healthful world. **In fact, if we want to ensure continued investment in these technologies, we should be very concerned about the message conveyed by the international political tide: if you overcome a challenging scientific problem and your solution has the potential to save lives, be prepared to be subjected to intense political pressure and to potentially hand over your technology without compensation and regardless of the consequences. The biotech industry is making remarkable advances towards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions.** President Biden is correct to refer to climate change as an existential crisis. **Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver).** “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” **If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course we dispute this notion), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis?** And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth?

United States Trade Representative (USTR) Katherine Tai was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties.

International Pressure May Be Influencing Domestic IP Policy The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The **Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists.** Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. **A TRIPS IP waiver would operate(s) outside**

of these types of frameworks. There would be no due process, no particularized findings, no compensation and no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver

would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), **it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so.** In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. **In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietary know-how to global competitors.** While it is unclear how this concept would work in practice and under the constitutions of certain countries, **the suggestion alone could be devastating to voluntary international collaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track** – with the assent of the U.S. government – **to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company.** Necessary Investment Could Diminish **Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight.** Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For **example, synthetic biology companies critical to this area of innovation raised over \$1 billion in investment in the second quarter of 2019 alone. If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels.** Next on the Chopping Block It is quite reasonable to be worried about the broad implications of a TRIPS IP waiver precedent. International campaigns to weaken IP rights seem to be taking hold in U.S. domestic policy. The TRIPS IP waiver discussions will not conclude in the near term and will not yield more shots in people’s arms. This is not even truly disputed, as our own administration acknowledges that the goal here is technology transfer abroad. **Given the signaling that our Administration believes waiving IP rights is an appropriate measure to end global crises, it is proper to worry that facets of the biotech sector addressing climate change may be [is] next on the chopping block.**

Warming exacerbates social inequalities, causes racism and gendered violence

Cuomo 11: (Chris Professor of Philosophy and Women's Studies, and an affiliate faculty member of the Environmental Ethics Certificate Program and the Institute for African-American Studies. The author and editor of many articles and several books in feminist, postcolonial, and environmental philosophy, Cuomo served as Director of the Institute for Women's Studies from 2006-2009. Her book, *The Philosopher Queen*, a reflection on post-9/11 anti-war feminist politics, was nominated for a Lambda Award and an APA book award, and her work in ecofeminist philosophy and creative interdisciplinary practice has been influential among those seeking to bring together social justice and environmental concerns, as well as theory and practice. She has been a recipient of research grants from the

Rockefeller Foundation, the National Science Foundation, the Ms. Foundation, the National Council for Research on Women, and the Institute for Sustainability and Technology Policy, and she has been a visiting faculty member at Cornell University, Amherst College, and Murdoch University in Perth, Australia, "Climate Change, Vulnerability, and Responsibility," Hypatia 26 no4 Fall 2011 p. 690-714, AM)

The aftermath of Hurricane Katrina made it plain that **structural inequalities produced by racism can determine who is most affected by severe weather events, and in turn disasters can greatly intensify social and political inequalities**. In addition, within nearly any society **the poorest and most vulnerable includes disproportionate numbers of females, people of color, and children**. Research shows that large-scale **disasters are especially devastating for those who lack economic and decision-making power**, and that "economic insecurity is a key factor increasing the impact of disasters on women as caregivers, producers, and community actors" (Enarson 2000, viii). But economic security is not the only factor influencing female vulnerabilities. **Existing social roles and divisions of labor can also set the stage for increased susceptibility to harm**. The tsunami that struck Asia in late 2004 resulted in a much greater loss of life among women and girls in many locations, because women "stayed behind to look for their children and other relatives; men more often than women can swim; men more often than women can climb trees," and at the time the waves struck, many men and boys were working in small boats or doing errands away from home (Oxfam 2005; see also American Congress of Obstetricians and Gynecologists 2006). **Extreme droughts, already occurring due to climate change, exacerbate gender inequalities in places where it is women's and girls' responsibility to gather daily water**, for when water becomes more scarce, **"many poor people, but particularly women and girls, will have to spend more time and energy fetching water from further away"** (Stern 2009, 70). **Physical hardship for women and girls is multiplied, but there are also auxiliary effects, such as decreased opportunities for girls to attend school and increased risk of assault** (American Congress of Obstetricians and Gynecologists 2006; Stern 2009; UN News Centre 2009). And **wealthier high emitters with running water are not immune to such ecological pressures**. In southeast Australia previously prosperous farmers are suffering due to reduced water availability and accompanying distribution policies. Women married to men in farming families report that their burden is greatly increased, because drought reduces farm income, and when wages are needed women find more opportunities for off-farm work. **Some must travel far or temporarily relocate for employment, although their caretaking responsibilities remain. Male partners respond to the compounding impacts of loss of financial security, livelihood, and identity with increased incidences of depression and domestic violence** (Alston 2008). Not surprisingly, their vulnerabilities are also shaped by norms of sex and gender.

Innovation is Key to Combating Climate Change

ICC, 2015

ICC is therefore highly supportive of efforts by the United Nations (UN) and other intergovernmental organizations to **encourage[s] technological innovation** in general, and innovation in **environmentally sustainable technology** in particular. ICC **especially** supports

efforts aimed at creating effective policy and regulatory environments around the world that encourage innovation and enable the development, broad dissemination, and use of innovative products and technologies.

To achieve its aims to find solutions for fighting climate change and adapting to its effects, the UN Framework Convention on Climate Change (UNFCCC) and its Parties must provide a framework which supports and encourages innovation. Fostering innovation is one of the post-2015 Sustainable Development Goals and is supportive of achieving other sustainable development goals, such as ending poverty and hunger, ensuring access to energy and health and promoting sustainable economic growth. The UNFCCC should embrace and support the development of positive technology enabling environments, innovation-focused government and market policies and regulation, as well as a more active and engaged role of the business community at large.

An effective response to climate change requires clean innovation on a global scale, i.e., the development and diffusion of a broad variety of new clean technologies in both developed and developing countries.

- There is broad consensus that clean technology innovation is key to addressing the global challenge of climate change. Indeed, many existing clean technologies already deliver considerably improved environmental performance compared to other technologies. In particular, they are more protective of the environment, display lower pollution levels, deploy resources in a more sustainable manner, recycle a higher share of their wastes and products, and/or treat residual wastes in an environmentally more acceptable way.
- Clean technologies fall into two categories: mitigation and adaptation. Mitigation technologies aim to reduce emissions of greenhouse gases or to capture them, while adaptive technologies allow users to adjust to negative effects of climate change, or exploit positive ones.
- Innovation comprises two dimensions: technology development and technology diffusion. Technology development refers to the use of scientific knowledge to obtain solutions. By contrast, technology diffusion is the process by which new technologies are transmitted from one party to another. Climate-friendly technologies, no matter how advanced, clearly do not serve their purpose until they

are actually deployed and used. A meaningful solution requires the world to collectively embrace a broad array of clean technology solutions, many of which are already widely available on the market today.

- Many clean technology solutions are already being developed and deployed by private sector actors.^{iv} Indeed, in most instances, a range of technological solutions are available from a range of market players, who compete amongst each other to address the same core sets of mitigation or adaptation challenges. The markets, in this sense are properly functioning, although in numerous situations trade barriers continue to cause prices to be higher than they would otherwise be.
- Technologies are also being transferred and shared, through commercial partnerships, collaborative innovation frameworks, and bilateral or regional government-to-government or private sector technology and innovation partnerships.

Response to Aff.

Squo solves – plan increases price of scarce materials and results in costly, ineffective facilities

Mcmurry-Heath 8/18 (Michelle Mcmurry-Heath, [physician-scientist and president and CEO of the Biotechnology Innovation Organization.], 8-18-2021, “Waiving intellectual property rights would harm global vaccination”, STAT, accessed: 8-19-2021, <https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/>) ajs

Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the **IP waiver**, it could **make** these **vaccines more expensive.**

Here’s why. Before Covid-19 emerged, the world produced at most 5.5 billion doses of various vaccines every year. Now **the world needs an additional 11 billion doses** — including billions of doses **of mRNA**

vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease.

Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of \$40 to \$100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months.

The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn't as easy as following a recipe from Bon Appetit.

Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.

Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about \$700 million, takes many months — if not years — to build and, once opened, requires another four to six months to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn't be until well into 2023 or later that any additional doses would become available.

That's slower than our current production rate. According to a report from Duke University's Global Health Innovation Center, companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity.

Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world's highest vaccination rates, paid \$23.50 per dose for early shipments, for a total of about \$315 million. That's approximately equal to the gross domestic productivity losses incurred during just two days of shutdowns in the country.

Many countries are buying shots for under \$10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just \$8 and \$5.25 per dose, respectively. For reference, a regular flu shot costs about \$14 in the United States, and pediatric vaccines average about \$55 per dose.

Meanwhile, low-income countries that can't afford even modest prices are getting their vaccines at no charge. COVAX, the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year.

President Biden vowed to make America the world's "arsenal of vaccines." **The U.S. has already committed \$4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate 500 million more by the end of summer. Other countries are following the administration's leadership and ramping up their donations.**

IPR hasn't harmed access – manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review", No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in "conflict diamonds". 26

Although the IP waiver proposal states that "there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients", 27 the sponsors did not provide further elaboration or evidence to support their declaration that "many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]". 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make **the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.** 30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18). 31

While much has been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,³² these **criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.**

Moreover, **while the disparity in pricing is concerning** the overall per dosage rate South Africa is **paying** nevertheless **represents value for money given the expected health and economic returns on investment.** Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at **unquestionably reasonable prices.**

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.³³ **Patents cannot be the problem in the countries where no patent applications have been filed,** but the lack of production in such countries points to the real problem – **these countries lack manufacturing capacity and capability.**

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such **factories and logistics exist in only a handful of countries.**³⁴ **Regardless of whether an IP waiver is granted,** the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With **prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices.** Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, **the waiver would simply serve to benefit advanced generic manufacturers,** most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

Waivers fail – license agreements are key to access and scaling up vaccines

Crosby et al 21 [Daniel Crosby, Evan Diamond, Isabel Fernandez de la Cuesta, Jamieson Greer, Jeffrey Telep, Brian White] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such **license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand,** and not for other purposes. **License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may**

be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.