## FW

#### The standard is maximizing expected wellbeing.

#### 1] Pleasure is intrinsically valuable and pain is intrinsically disvaluable

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

Let us start by observing, empirically, that **a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable.** **On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues.** This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have.** “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 **The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values.** If you tell me that you are heading for the convenience store, **I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so**, not merely for the sake of going to the convenience store, but **for the sake of achieving something further that you deem to be valuable.** You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” **If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.**3 As Aristotle observes**: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.**”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value.**

#### 2] Moreover, *only* pleasure and pain are intrinsically valuable. All other values can be explained with reference to pleasure; Occam’s razor requires us to treat these as instrumentally valuable.

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

I think several things should be said in response to Moore’s challenge to hedonists. First, **I do not think the burden of proof lies on hedonists to explain why the additional values are not intrinsic values. If someone claims that X is intrinsically valuable, this is a substantive, positive claim, and it lies on him or her to explain why we should believe that X is in fact intrinsically valuable.** Possibly, this could be done through thought experiments analogous to those employed in the previous section. Second, **there is something peculiar about the list of additional intrinsic values** that counts in hedonism’s favor**: the listed values have a strong tendency to be well explained as things that help promote pleasure and avert pain.** To go through Frankena’s list, life and consciousness are necessary presuppositions for pleasure; activity, health, and strength bring about pleasure; and happiness, beatitude, and contentment are regarded by Frankena himself as “pleasures and satisfactions.” The same is arguably true of beauty, harmony, and “proportion in objects contemplated,” and also of affection, friendship, harmony, and proportion in life, experiences of achievement, adventure and novelty, self-expression, good reputation, honor and esteem. Other things on Frankena’s list, such as understanding, **wisdom, freedom, peace, and security, although they are perhaps not themselves pleasurable, are important means to achieve a happy life, and as such, they are things that hedonists would value highly.** **Morally good dispositions and virtues, cooperation, and just distribution of goods and evils, moreover, are things that, on a collective level, contribute a happy society, and thus the traits that would be promoted and cultivated if this were something sought after.** To a very large extent, the intrinsic values suggested by pluralists tend to be hedonic instrumental values. Indeed, pluralists’ suggested intrinsic values all point toward pleasure, for while the other values are reasonably explainable as a means toward pleasure, pleasure itself is not reasonably explainable as a means toward the other values. Some have noticed this. Moore himself, for example, writes that though his pluralistic theory of intrinsic value is opposed to hedonism, its application would, in practice, look very much like hedonism’s: “Hedonists,” he writes “do, in general, recommend a course of conduct which is very similar to that which I should recommend.”24 Ross writes that “[i]t is quite certain that by promoting virtue and knowledge we shall inevitably produce much more pleasant consciousness. These are, by general agreement, among the surest sources of happiness for their possessors.”25 Roger Crisp observes that “those goods cited by non-hedonists are goods we often, indeed usually, enjoy.”26 What Moore and Ross do not seem to notice is that their observations give rise to two reasons to reject pluralism and endorse hedonism. The first reason is that if **the suggested non-hedonic intrinsic values are potentially explainable by appeal to just pleasure and pain** (which, following my argument in the previous chapter, we should accept as intrinsically valuable and disvaluable), **then—by appeal to Occam’s razor—we have at least a pro tanto reason to resist the introduction of any further intrinsic values and disvalues. It is ontologically more costly to posit a plurality of intrinsic values and disvalues, so in case all values admit of explanation by reference to a single intrinsic value and a single intrinsic disvalue, we have reason to reject more complicated accounts.** **The fact that suggested non-hedonic intrinsic values tend to be hedonistic instrumental values does not, however, count in favor of hedonism solely in virtue of being most elegantly explained by hedonism; it also does so in virtue of creating an explanatory challenge for pluralists.** The challenge can be phrased as the following question: **If the non-hedonic values suggested by pluralists are truly intrinsic values in their own right, then why do they tend to point toward pleasure and away from pain?**27

#### 3] Actor specificity:

#### ---A] Aggregation – every policy benefits some and harms others, so side constraints freeze action.

#### ---B] States lack wills or intentions since policies are collective actions.

#### ---C] No act-omission distinction—governments are responsible for everything in the public sphere, so inaction is implicit authorization of action: they have to yes/no bills, which means everything collapse to aggregation.

#### ---D] Actor-specificity first since different agents have different ethical standings. Link turns calc indicts because the alt would be *no* action.

#### 4] Lexical pre-requisite: threats to bodily security preclude the ability for moral actors to effectively act upon other moral theories since they are in a constant state of crisis that inhibits the ideal moral conditions which other theories presuppose

#### 5] Use epistemic modesty – that’s multiplying the probability of a framework being true by its general contention impact –

#### ---A] It maximizes the probability of achieving net most moral value—beating a framework acts as mitigation to their impacts but the strength of that mitigation is contingent

#### ---B] EC is too high a burden—thousands of years of philosophy can’t be resolved in 40 minutes.

#### ---C] Topic education—disincentives debaters from going all in for framework which means we get the ideal balance between topic ed and phil ed—it’s important to talk about contention-level offense because we only have the topic for two months.

#### ---D] Clash — we don’t know if our frameworks are true, but we can debate the topical question. That incentivizes debating both layers instead of solely focusing on framework.

Death and the process is prereq to sv

## 1

#### Member nations of the WTO should:

#### Institute value-based pricing for new medicines

#### Allow health service agencies to negotiate over drug prices

#### Institute price increase caps on existing drugs to an international reference price

#### Set aside public funding in the form of Development Impact Bonds and cash-on-delivery tied to health gain and encourage risk-sharing for NTD research

#### Engage in health diplomacy where richer nations share medicines and information to poorer nations to combat neglected diseases

#### Planks 1-3 solve drug prices but avoids the patent good turns.

**Rajkumar 2020** (S. Vincent Rajkumar, MD, Division of Hematology, Mayo Clinic, Rochester, MN (S.V.R.). “The high cost of prescription drugs: causes and solutions” *Blood Cancer Journal* volume 10, Article number: 71 2020)DR 21

Value-based pricing

Unlike other developed countries, the United States does not negotiate over the price of a new drug based on the value it provides. This is a fundamental problem that allows drugs to be priced at high levels, regardless of the value that they provide. Thus, almost every new cancer drug introduced in the last 3 years has been priced at more than $100,000 per year, with a median price of approximately $150,000 in 2018. The lack of value-based pricing in the United States also has a direct adverse effect on the ability of other countries to negotiate prices with manufacturers. It greatly reduces leverage that individual countries have. Manufacturers can walk away from such negotiations, knowing fully well that they can price the drugs in the United States to compensate. A governmental or a nongovernmental agency, such as the Institute for Clinical and Economic Review (ICER), must be authorized in the United States by law, to set ceiling prices for new drugs based on incremental value, and monitor and approve future price increases. Until this is possible, the alternative solution is to cap prices of lifesaving drugs to an international reference price.

Medicare negotiation

In addition to not having a system for value-based pricing, the United States has specific legislation that actually prohibits the biggest purchaser of oral prescription drugs (Medicare) from directly negotiating with manufacturers. One study found that if Medicare were to negotiate prices to those secured by the Veterans Administration (VA) hospital system, there would be savings of $14.4 billion on just the top 50 dispensed oral drugs[17](https://www.nature.com/articles/s41408-020-0338-x#ref-CR17).

Cap on price increases

The United States also has a peculiar problem that is not seen in other countries: marked price increases on existing drugs. For example, between 2012 and 2017, the United States spent $6.8 billion solely due to price increases on the existing brand name cancer drugs; in the same period, the rest of the world spent $1.7 billion less due to decreases in the prices of similar drugs[18](https://www.nature.com/articles/s41408-020-0338-x#ref-CR18). But nothing illustrates this problem better than the price of insulin[19](https://www.nature.com/articles/s41408-020-0338-x#ref-CR19). One vial of Humalog (insulin lispro), that costs $21 in 1999, is now priced at over $300. On January 1, 2020, drugmakers increased prices on over 250 drugs by approximately 5%[20](https://www.nature.com/articles/s41408-020-0338-x#ref-CR20). The United States clearly needs state and/or federal legislation to prevent such unjustified price increases [21](https://www.nature.com/articles/s41408-020-0338-x#ref-CR21).

#### Plank 4 and 5 solves NTDs and Health diplomacy BUT pharma profits are key—NTD research is high-risk and capital-intensive

**Barofksy and Schneider 2017** (Jeremy Barofsky, Sc.D., M.A. is a non-resident Fellow in Governance Studies at the Brookings Institution and a Research Associate at Tulane University’s Commitment to Equity (CEQ) Institute. He received his doctorate from Harvard University’s T.H. Chan School of Public Health in Global Health and Population (Economics) and holds an M.A. in Economics from Boston University. and Jake Schneider, Research Assistant - The Brookings Insitution “Promoting Private Sector Involvement in Neglected Tropical Disease Research and Development” *The Brookings Private Sector Global Health R&D Project* https://www.brookings.edu/wp-content/uploads/2017/12/br\_health4\_optimized\_final.pdf December 2017)DR 21

Based on this analysis, we make several recommendations for future action:

1. Alignment of public funding with social return. Our analysis shows the restricted circumstances in which private sector R&D generates a positive return on investment in the current policy environment. To increase the range of activities that receive private funding, **we propose public funding that is explicitly tied to health gain** (disability adjusted life years [DALYs] averted). There are various financing mechanisms that have been developed that would allow governments to pay for results, including Development Impact Bonds and cash-on-delivery models. These arrangements allow public funders to provide financing contingent on results, as verified by a third party, and do not require outlays otherwise.
2. Private sector late-stage investment and risk sharing. Our quantitative analysis finds that the most important drivers of private sector development cost are long development timelines and failure risk. Complementary to recommendation #1, we therefore propose additional private sector investment focused on phase III clinical trials to minimize risk-adjusted, capitalized private sector costs. In addition, to further minimize risk, private sector **biopharmecutical firms could enter into investment agreements that would spread the risk** and benefits of these trials. This risk-sharing arrangement would be particularly oriented toward social impact investors that want to both diversify market risk (R&D risk being orthogonal to market risk) and generate positive social returns.
3. Public funding coordination and stewardship. Our case studies indicated the importance of stewardship and coordination of product development partnerships by non-profit entities. Greater stewardship from governments to determine priority areas for NTD investment as well as coordinate joint funding of early stage R&D with nonprofit actors would both increase the likelihood of private sector involvement in late stage R&D as well as increase the likelihood that innovation maximizes public health.
4. Advanced market commitment for hookworm and schistosomiasis: Our analysis highlighted the challenges for NTD vaccine development and the mismatch in scale between current resources compared to the funding necessary for successful development. The creation of an advanced market commitment ensuring a set price for certain number of treatments purchased would increase the likelihood of private involvement in vaccine development.
5. Tiered PRV based on social return and clinical stage: One specific policy change that may be more feasible in the near term to align financial incentives and health impact includes an adjustment to the PRV such that the PRV varies based on the level of innovation produced compared to current clinical practice.

## 2

#### The United States should publicly repudiate waivers.

#### Current IP protections protect investment in climate change reduction – COVID and medicines waiver spills over to reduce innovation

Brand 5/26 [Melissa Brand is Assistant General Counsel and Director of Intellectual Property at the Biotechnology Innovation Organization (BIO), a major trade association with over 1,000 members in the biotechnology industry. May 26, 2021, “TRIPS IP Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors,” ipwatchdog, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964//lhs-ap]

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 amorphously) 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 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 next on the chopping block.

#### Extinction

Dr. Yew-Kwang Ng 19, Winsemius Professor of Economics at Nanyang Technological University, Fellow of the Academy of Social Sciences in Australia and Member of Advisory Board at the Global Priorities Institute at Oxford University, PhD in Economics from Sydney University, “Keynote: Global Extinction and Animal Welfare: Two Priorities for Effective Altruism”, Global Policy, Volume 10, Number 2, May 2019, pp. 258–266

Catastrophic climate change Though by no means certain, CCC causing global extinction is possible due to interrelated factors of non-linearity, cascading effects, positive feedbacks, multiplicative factors, critical thresholds and tipping points (e.g. Barnosky and Hadly, 2016; Belaia et al., 2017; Buldyrev et al., 2010; Grainger, 2017; Hansen and Sato, 2012; IPCC 2014; Kareiva and Carranza, 2018; Osmond and Klausmeier, 2017; Rothman, 2017; Schuur et al., 2015; Sims and Finnoff, 2016; Van Aalst, 2006).7 A possibly imminent tipping point could be in the form of ‘an abrupt ice sheet collapse [that] could cause a rapid sea level rise’ (Baum et al., 2011, p. 399). There are many avenues for positive feedback in global warming, including: • the replacement of an ice sea by a liquid ocean surface from melting reduces the reflection and increases the absorption of sunlight, leading to faster warming; • the drying of forests from warming increases forest fires and the release of more carbon; and • higher ocean temperatures may lead to the release of methane trapped under the ocean floor, producing runaway global warming. Though there are also avenues for negative feedback, the scientific consensus is for an overall net positive feedback (Roe and Baker, 2007). Thus, the Global Challenges Foundation (2017, p. 25) concludes, ‘The world is currently completely unprepared to envisage, and even less deal with, the consequences of CCC’. The threat of sea-level rising from global warming is well known, but there are also other likely and more imminent threats to the survivability of mankind and other living things. For example, Sherwood and Huber (2010) emphasize the adaptability limit to climate change due to heat stress from high environmental wet-bulb temperature. They show that ‘even modest global warming could ... expose large fractions of the [world] population to unprecedented heat stress’ p. 9552 and that with substantial global warming, ‘the area of land rendered uninhabitable by heat stress would dwarf that affected by rising sea level’ p. 9555, making extinction much more likely and the relatively moderate damages estimated by most integrated assessment models unreliably low. While imminent extinction is very unlikely and may not come for a long time even under business as usual, the main point is that we cannot rule it out. Annan and Hargreaves (2011, pp. 434–435) may be right that there is ‘an upper 95 per cent probability limit for S [temperature increase] ... to lie close to 4°C, and certainly well below 6°C’. However, probabilities of 5 per cent, 0.5 per cent, 0.05 per cent or even 0.005 per cent of excessive warming and the resulting extinction probabilities cannot be ruled out and are unacceptable. Even if there is only a 1 per cent probability that there is a time bomb in the airplane, you probably want to change your flight. Extinction of the whole world is more important to avoid by literally a trillion times.

# Case

### WTO Can’t Solve:

#### Aff gets circumvented- powerful countries use bilateral agreements to force other countries to accept their IPR protections- its empirically proven

DC = developing country

NIT = Net Importers of Technology (this references developing countries)

NET = Net Exporters of Technology (countries with advanced economies)

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016./SJKS

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on October 20, 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory measure in connection with an IP issue; that this type of action seriously inhibited Brazil’s participation in the work of the Group, since ‘no country could be expected to participate in negotiations while experiencing pressures on the substance of its position’ (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment of the Punta del Este Declaration. ‘The United States action was an attempt to coerce Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round’ (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted, and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28). The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil’s economy would likely affect their co-operation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos and Braithwaite 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

### Patents Don’t Solve

#### Patents can’t solve the vaccine problem- they don’t have enough info and manufacturers shield key replication information

Santos Rutschman 21 Santos Rutschman, Ana (Professor of Law, St. Louis University) and Julia Barnes-Weise (Executive Director of the Global Healthcare Innovation Alliances Accelerator a non-profit organization spun out of a program in Public Policy at Duke University, and a Senior Consultant to the Coalition for Epidemic Preparedness Innovations. She is a lawyer, global health policy consultant, entrepreneur and Certified Licensing Professional). "The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal." Bill of Health (2021) (2021)./SJKS

In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem. First, we are still left with a significant informational problem: as many [commentators](https://science.sciencemag.org/content/369/6506/912) have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine. From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere.

### Global Manufacturing Fails

#### Raw materials take years to scaleup.

Newey et al 21 [Sarah Newey*;* Anne Gulland*;* Jennifer Rigby, (GLOBAL HEALTH SECURITY CORRESPONDENTS at the telegraph) *and* Samaan Lateef (Reporting IN INDIA) 6/1/21, Vaccinating the world: the obstacles hindering global rollout – and how to overcome them, Telegraph, <https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/>] Justin

But perhaps the strongest argument against waivers is this: in October Moderna, one of the producers of new mRNA vaccines, actually offered an IP waiver. No-one has yet taken it up. Instead, “the biggest obstacle is raw materials,” says Dr Richard Torbett, chief executive of the Association of the British Pharmaceutical Industry. “All of the companies are saying we could produce more if we only had more glass vials, or filters, or bio bags.” Again, this is a daunting challenge – the Pfizer vaccine, for example, has 260 ingredients that come from 60 companies in 19 different countries. Many of these products are highly specialised and it will take many months, perhaps years, to ramp production of them up. “We’re very likely to see continued shortages that set back some of the vaccine producers for several months,” says Rasmus Bech Hansen, chief executive of Airfinity, adding that it is becoming harder for manufacturers with new jabs to secure the needed supplies – CureVac is already facing this problem, for example. The third challenge is perhaps harder to tackle. Vaccines are biological products and the manufacturing process does not always go smoothly. According to Airfinity, 1.73bn doses have been distributed worldwide, far short of the 4.5bn initially projected by big pharma. An overambitious manufacturing target is largely to blame for the gap. [AstraZeneca’s row with Europe](https://www.telegraph.co.uk/news/2021/05/09/eu-says-wont-renew-astrazeneca-contract-pivots-towards-pfizers/), for instance, was triggered by a lower yield at factories than hoped. Meanwhile Russia has produced only around 42m doses – compared to 400m from AstraZeneca and Pfizer – amid difficulties producing the second dose of Sputnik V, which uses different adenoviruses in the first and second shot.