# 1st off

#### I value morality. Ethical Internalism is true:

#### 1. Epistemology – A) Equality – Externalism incorrectly assumes certain individuals have stronger epistemic access to moral truths which justifies the exclusion of those individuals from the creation of ethics and B) Inaccessibility – There is no universal character of moral judgements that is epistemically accessible since every argument for its existence presumes the correct normative starting point. Markovits 14, Markovits, Julia. Moral reason. Oxford University Press, 2014.//Scopa Relatedly, internalism about reasons seems less presumptive than externalism. We should not assume that some of us have special epistemic access to what matters, especially in the absence of any criterion for making such a judgment. It’s better to start from the assumption, as internalism does, that everyone’s ends are equally worthy of pursuit – and correct this assumption only by appealing to standards that are as uncontroversial as possible. According to externalism about reasons, what matters normatively – that is, what we have reason to do or pursue or protect or respect or promote – does not depend in any fundamental way on what in fact matters to us – that is, what we do do and pursue and protect and respect and promote. Some of us happen to be motivated by what actually matters, and some of us are “wrongly” motivated. But externalists can offer no explanation for this supposed difference in how well we respond to reasons – no explanation of why some of us have the right motivations and some of us the wrong ones – that doesn’t itself appeal to the views about what matters that they’re trying to justify. (They can explain why some people have the right motivations by saying, e.g., that they’re good people, but that assumes the truth of the normative views that are at issue.22) A comparison to the epistemic case helps bring out what is unsatisfactory in the externalist position. We sometimes attribute greater epistemic powers to some people than to others despite not being able to explain why they’re more likely to be right in their beliefs about a certain topic. Chicken-sexing is a popular example of this among philosophers. We think some people are more likely to form true beliefs about the sex of chickens than others even though we can’t explain why they are better at judging the sex of chickens. But in the case of chicken-sexing, we have independent means of determining the truth, and so we have independent verification that chicken-sexers usually get things right. Externalism seems to tell[s] us that some of us are better reasons- sensors than others, but without providing the independent means of determining which of us are in fact more reliably motivated by genuine normative reasons (or even that some of us are).

#### 2. Motivation – A) Externalist notions of ethics collapse to internal since the only reason agents follow external demands is those demands are consistent with their internal account of the good. Motivation is a necessary feature for ethics since normativity only matters insofar as agents follow through on the ethic that’s generated from it B) Empirics – there is no factual account of the good since each agents’ motivations are unique and there has been no conversion of differing beliefs into a unified ethic.

#### Thus, agents justify their actions based on individual moral preferences and deal with ethical dilemmas by prioritizing certain beliefs. It’s a constitutive feature of humanity to rationally maximize value under a particular index of the good. Gauthier 98, David Gauthier, Canadian-American philosopher best known for his neo-Hobbesian social contract theory of morality, Why Contractarianism?, 1998, ///AHS PB //Recut by Scopa Fortunately, I do not have to defend normative foundationalism. One problem with accepting moral justification as part of our ongoing practice is that, as I have suggested, we no longer accept the world view on which it depends. But perhaps a more immediately pressing problem is that we have, ready to hand, an alternative mode for justifying our choices and actions. In its more austere and, in my view, more defensible form, this is to show that choices and actions maximize the agent ’s expected utility, where utility is a measure of considered preference. In its less austere version, this is to show that choices and actions satisfy, not a subjectively defined requirement such as utility, but meet the agent ’ s objective interests. Since I do not believe that we have objective interests, I shall ignore this latter. But it will not matter. For the idea is clear; we have a mode of justification that does not require the introduction of moral considerations. 11 Let me call this alternative nonmoral mode of justification, neutrally, deliberative justification. Now moral and deliberative justification are directed at the same objects – our choices and actions. What if they conflict? And what do we say to the person who offers a deliberative justification of his choices and actions and refuses to offer any other? We can say, of course, that his behavior lacks moral justification, but this seems to lack any hold, unless he chooses to enter the moral framework. And such entry, he may insist, lacks any deliberative justification, at least for him. If morality perishes, the justificatory enterprise, in relation to choice and action, does not perish with it. Rather, one mode of justification perishes, a mode that, it may seem, now hangs unsupported. But not only unsupported, for it is difficult to deny that deliberative justification is more clearly basic, that it cannot be avoided insofar as we are rational agents, so that if moral justification conflicts with it, morality seems not only unsupported but opposed by what is rationally more fundamental. Deliberative justification relates to our deep sense of self. What distinguishes human beings from other animals, and provides the basis for rationality, is the capacity for semantic representation. You can, as your dog on the whole cannot, represent a state of affairs to yourself, and consider in particular whether or not it is the case, and whether or not you would want it to be the case. You can represent to yourself the contents of your beliefs, and your desires or preferences. But in representing them, you bring them into relation with one another. You represent to yourself that the Blue Jays will win the World Series, and that a National League team will win the World Series, and that the Blue Jays are not a National League team. And in recognizing a conflict among those beliefs, you find  rationality thrust upon you. Note that the first two beliefs could be replaced by preferences, with the same effect. Since in representing our preferences we become aware of conflict among them, the step from representation to choice becomes complicated. We must, somehow, bring our conflicting desires and preferences into some sort of coherence. And there is only one plausible candidate for a principle of coherence – a maximizing principle. We order our preferences, in relation to decision and action, so that we may choose in a way that maximizes our expectation of preference fulfillment. And in so doing, we show ourselves to be rational agents, engaged in deliberation and deliberative justification. There is simply nothing else for practical rationality to be. The foundational crisis of morality thus cannot be avoided by pointing to the existence of a practice of justification within the moral framework, and denying that any extramoral foundation is relevant. For an extramoral mode of justification is already present, existing not side by side with moral justification, but in a manner tied to the way in which we unify our beliefs and preferences and so acquire our deep sense of self. We need not suppose that this deliberative justification is itself to be understood foundationally. All that we need suppose is that moral justification does not plausibly survive conflict with it.

**Since agents take their own ability to act as intrinsically valuable, permissibility is avoided through a system of mutual self restraint where agents refrain from impeding upon the actions of other agents, under the expectation that others will do the same out of rational self interest. This is achieved through a system of contracts which both parties’ consent to in order to regulate behavior.**

#### Thus, the standard is consistency with Contractarianism. And, the framework outweighs on actor specificity: States are not physical actors, but derive authority from contracts that allow them to constrain action.

#### Prefer additionally –

#### 1. Flexibility – Contracts are key to a) Encompassing all other ethical calculus into our decision since we process the consistency of those frameworks with our self interest and b) Value pluralism – recognizing a singular ethic fails to account for the complexity of moral problems and genuine moral disagreement. My framework solves since we can recognize multiple legitimate values while allowing individuals to exclude ones that are bad.

#### 2. Bindingness – A) Arising of Ethics – Every interaction with another agent is mediated by consent to participate in that interaction since otherwise agents could simply leave, which means there is an implicit social contract formed in every ethical interaction and B) Culpability – Only contracts can ensure agents are held to their agreements since there is a verifiable basis for judging their action as wrong as well as a pre-established punishment for breaking it.

## Contention

#### I contend that the member nations of the World Trade Organization ought not reduce intellectual property protections for medicines.

#### [1] Stronger IPRs help equalize the bargaining field for developing countries to check western coercion which would diminish their place as world enforcer. Therefore, it’s not in mutual self-interest for them to remove IPs because they want to keep their own economies ahead of others.

**Hassan et al 10** “Intellectual Property and Developing Countries: A review of the literature: by Emmanuel Hassan, Ohid Yaqub, Stephanie Diepeveen. RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. [https://www.rand.org/content/dam/rand/pubs/technical\_reports/2010/RAND\_TR804.pdf] // ahs emi

Commonly, FDI and trade are seen as key determinants for economic development and poverty reduction in developing countries. Inward FDI can generate important spillovers for developing economies, resulting in the upgrading of domestic innovative capacity, increased R&D employment, better training and support to education. For most developing countries, international trade allows them to acquire high value-added goods through importation that are necessary for economic development, but which are not produced domestically. In turn, exports allow developing countries to transform underutilised natural resources and surplus labour into foreign exchange, in order to pay for imports to support economic growth. Consequently, a central aim of the literature has been to examine how **stronger IPRs in developing countries can give incentives to firms in developed countries to undertake cross-border investment in, and to export their goods** to, these countries. Recalling the ambiguous relationship between IPRs and the individual strategies of single firms from a theoretical point of view, researchers have investigated empirically the effects of stronger IPRs on inward FDI in developing countries and exports from developed to developing countries. The empirical **evidence suggests that** **stronger IPRs may positively affect the volume of FDI and exports, particularly in countries with strong technical absorptive capabilities where the risk of imitation is high. When such risk is weak, particularly in the poorest countries, firms in developed countries do not seem to be sensitive to the level of protection in developing countries.** Using disaggregated data on FDI and trade, the empirical literature also shows that stronger IPRs impact on the composition of FDI and trade. First, stronger IPRs seem to encourage FDI in production and R&D rather than in sales and distribution. Second – and more surprisingly – stronger IPRs do not have any effect on the exports of hightechnology products. There are at least two explanations for this somewhat surprising result. Many high-tech products are difficult to imitate, thereby international trade for these products is less sensitive to the level of protection than for other products. Furthermore, firms in developed countries may choose to distribute their high-tech products through FDI or licensing, instead of exporting them directly. Intellectual property rights, international technology transfer and domestic innovation Increasingly, harnessing technological progress is viewed by policymakers as a key priority to boost economic growth and improve living standards. In an open economy, technological progress can be driven either by technology diffusion or technology creation. In less advanced economies, technology absorption can drive economic growth because countries at the forefront of technology act as a driver for growth by expanding the stock of scientific and technological knowledge, pulling other countries through a ‘catch-up’ effect. However, the strength of this ‘catch-up’ effect at the technology frontier decreases with the level of technological development, to the benefit of technology creation. Indeed, technology creation by domestic firms becomes progressively more important as a country moves closer to the technology frontier, because catching up with the frontier translates into increasingly smaller technological improvement**. The empirical literature has examined the effects of IPRs on technological progress through these two main channels: technology absorption (i.e. international technology transfer) and technology creation (i.e. domestic innovation).** The empirical evidence suggests that **stronger IPRs in developing countries may encourage international technology transfer** through market-based channels,1 particularly licensing, at least in countries with strong technical absorptive capacities. In the context of strong IPRs, **firms in developed countries are more inclined to transfer** their technologies to developing countries through licensing rather than through exports and FDI, **since such rights allow them to retain control over their technologies. In the presence of weak IPRs, multinationals in developed countries seem to prefer to retain control over their technologies** through intra-firm trade with their foreign affiliates in developing countries or FDI. Nevertheless, the historical evidence shows that many developing countries have benefited from international technology transfer through non-market-based channels, especially reverse engineering and imitation, thanks to weak IPR regimes. The empirical literature **also shows that** **stronger IPRs can encourage domestic innovation**, at least in emerging industrialised economies. Nevertheless, the empirical literature suggests the existence of a non-linear function (i.e. a U-shaped curve) between IPRs and economic development, which initially falls as income rises, then increases after that.

#### [2] IP rights are included in multiple international contracts – the aff violates that.

**Franklin 13** - “International Intellectual Property Law” by Jonathan Franklin\* He earned his A.B., A.M. Anthropology and J.D. degrees from Stanford University and M.Libr. with a Certificate in Law Librarianship from the University of Washington. Prior to the University of Washington, he spent five years as an reference librarian and foreign law selector at the University of Michigan Law Library. In law school, he was a Senior Editor of the Stanford Environmental Law Journal and a Note Editor for the Stanford Law Review. He is a member of the American Association of Law Libraries. [https://www.asil.org/sites/default/files/ERG\_IP.pdf] // ahs emi

The most important international **agreements in intellectual property** law are listed here. Many of them are available in multiple formats, **includ**ing Microsoft Word, PDF, and HTML. In addition, This page was last updated February 8, 2013. 5 the links below link to the main pages for those treaties, rather than the HTML texts so that the reader can also find related protocols, notifications and signatories. ● Agreement on Trade-Related Aspects of Intellectual Property Rights ("**TRIPS**")(http://www.wto.org/english/docs\_e/legal\_e/legal\_e.htm#TRIPs) ● Berne Convention for the Protection of Literary and Artistic Works (http://www.wipo.int/treaties/en/ip/berne/index.html) ● **Hague Agreement** Concerning the Deposit of Industrial Designs (http://www.wipo.int/hague/en/legal\_texts/) ● International Convention for the Protection of New Varieties of Plants(http://www.upov.int/en/publications/conventions/index.html) ● **Madrid Agreement** Concerning the International Registration of Trademark (http://www.wipo.int/madrid/en/legal\_texts/) ● Paris Convention for the Protection of Industrial Property (http://www.wipo.int/treaties/en/ip/paris/index.html) ● **Patent Cooperation Treaty** (http://www.wipo.int/pct/en/texts/index.htm) ● **Trademark Law Treaty** (http://www.wipo.int/treaties/en/ip/tlt/index.html) ● **Universal Copyright Convention** (http://portal.unesco.org/en/) For other substantive, registration and classification treaties, see the treaty sections at the World Intellectual Property Organization (WIPO) (http://www.wipo.int/clea/en/index.jsp), IPRsonline (http://www.iprsonline.org/legalinstruments/international.htm), the Compleat World Copyright Web site (http://www.compilerpress.ca/CW/multi\_i.htm) and the intellectual property page at the Electronic Information System for International Law (EISIL) (http://www.eisil.org/). For bilateral treaties, one of the best sources is IPRsonline(http://www.iprsonline.org/legalinstruments/bilateral.htm). The focus of this Chapter is international law. Although it includes references to national domestic law (foreign law) **and** comparative law sources, other sites comprehensively cover national domestic law, such as WIPO’s Collection of Laws for Electronic Access (CLEA)(http://www.wipo.int/clea/en/index.jsp) (which is also referred to as WIPO Lex) or UNESCO’s Collection of National Copyright Laws(http://portal.unesco.org/culture/en/). For **additional** web sites that compile **national** intellectual property **laws** and decisions, see the relevant 6 section below. Practical Law Company’s Cross-border: Intellectual Property & Technology (http://us.practicallaw.com/about/cross-border-intellectual-property-technology) provides a substantial list of country comparisons touching on intellectual property law.

#### [3] Forecloses the ability for future contracts.

Hilty et al 21 [Reto Hilty Director at the Max Planck Institute for Innovation and Competition and a professor at the University of Zurich Pedro Henrique D. Batista Doctoral student and Junior Research Fellow at the Max Planck Institute for Innovation and Competition Suelen Carls Senior Research Fellow at the Max Planck Institute for Innovation and Competition Daria Kim Senior Research Fellow at the Max Planck Institute for Innovation and Competition Matthias Lamping Senior Research Fellow at the Max Planck Institute for Innovation and Competition Peter R. Slowinski Doctoral student and Junior Research Fellow at the Max Planck Institute for Innovation and Competition; “10 Arguments against a Waiver of Intellectual Property Rights,” Oxford Law; 6/29/21; <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>] Justin

2. Intellectual property rights are the **basis for collaborations and contracts** The development cycle of the new mRNA and vector vaccines—from the provision of the technological basis to safety studies and marketing authorisation—is tremendously multifaceted. Nevertheless, throughout the development, production and distribution of vaccines against Covid-19, cooperation has reached an **unprecedented** level—despite the typically fierce competition in the biopharmaceutical sector. Intellectual property rights and particularly patents are normally the basis for such cooperation; they provide assurance that contracts will be **fulfilled. Even a temporary waiver** of these rights may therefore have **detrimental consequences for the willingness to cooperate**.

No alt fwk means auto neg ballot.

# Case

#### [1] Util creates a moral obligation to oppress people, when their suffering would cause a greater amount of happiness for the majority.

Jeffrey **Gold**, Utilitarian and Deontological Approaches to Criminal Justice Ethics

According to utilitarianism, an action is moral when it produces the great-est amount of happiness for the greatest number of people. A problem arises, however, when the greatest happiness is achieved at the expense of a few. For example, **if a large group were to enslave a very small group, the large group would gain certain comforts and luxuries (and the pleasure that accompanies those comforts) as a result of the servitude of the few**. **If we were to follow the utilitarian calculus** strictly, **the suffering of a few (even intense suffering) would be outweighed by the pleasure of a large enough majority**. A thousand people’s modest pleasure would outweigh the suffer-ing of 10 others. Hence, utilitarianism would seem to endorse slavery when it produces the greatest total amount of happiness for the greatest number of people. This is obviously a problem for utilitarianism. **Slavery and oppression are wrong regardless of the amount of pleasure accumulated by the oppressing class. In fact, when one person’s pleasure results from the suf-fering of another, the pleasure seems all the more abhorrent.** The preceding case points to a weakness in utilitarianism, namely, the weak-ness in dealing with certain cases of injustice. Sometimes it is simply unjust to treat people in a certain way regardless of the pleasurable consequences for others. A gang rape is wrong even if 50 people enjoy it and only one suffers. It is wrong because it is unjust. To use Kant’s formulation, it is always wrong to treat anyone as a mere means to one’s own ends. When we enslave, rape, and oppress, we are always treating the victim as a means to our own ends.

#### They read morally repugnant arguments. Thus the alternative is to drop the debater, to ensure that debate remains a space safe for all – the judge has a proximal obligation to ensure inaccessible practices don’t proliferate. Accessibility is a voting issue since all aff arguments presuppose that people feel safe in this space to respond to them.

#### 1] A vaccine waiver greenlights counterfeit medicine – independently turns Case by increasing vaccine hesitancy.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### 2] Lack of key supplies

Tepper 21 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

#### 3] Hurts Innovation

**Value Ingenuity 20** [Value Ingenuity, (The Value Ingenuity project is telling the story of innovation, its roots, its impact, its social and moral imperatives, and the public policy prescriptions that will assure a continued upward trajectory for the generations to follow. Our objective is to advance globally a shared purpose of mutual investment in sustainable innovation.)]. "WTO IP Waiver Would Undermine Covid Innovation." 10-2-2020, Accessed 8-5-2021. https://www.valueingenuity.com/2021/05/18/wto-ip-waiver-would-undermine-covid-innovation/ // duongie

A TRIPS waiver for vaccines would do nothing to help — and could in fact hurt — the effort to produce billions of vaccine doses and get them in arms. Supply of these high-tech products is ramping up quickly, with about 10 billion doses projected to be produced by the end of 2021 — we shouldn’t distract attention away from that all-important goal. IP is not a barrier to vaccine access. It already enabled the creation of three vaccines, in record-breaking time, that have received FDA authorization. IP is also safely facilitating international partnerships (275+ to date) to share technology and information more easily with trusted partners across borders. An IP waiver could lead to untested and unregulated copycats. Some nations are looking to manufacture sophisticated vaccines without permission, exacerbating the shortage of the critical materials (raw materials, tubing, vials etc.) and increasing vaccine hesitancy due to the development of unsafe products and medicines. The proposal jeopardizes U.S. manufacturing & jobs. Allowing other countries to take and commercialize American-made technologies conflicts with President Biden’s goal to build up American infrastructure and create manufacturing jobs. In the U.S. alone, biopharmaceutical companies support 4 million jobs across all 50 states, with many more across innovation ecosystems in labs, finance, and SMEs. Waiving IP undermines America’s leadership in the life sciences. We should not be forfeiting IP to countries looking to undermine America’s global leadership in biomedical technology and innovation. IP protections enabled decades of R&D by biopharmaceutical research companies, allowing them to move quickly and effectively against COVID-19. Business welcomes the Biden Administration’s support for the global vaccine program, COVAX. This type of program can have a significant positive, practical impact on global rollout of vaccines and therapies without disrupting the incredible IP-enabled progress that has been made to date to defeat the pandemic. Its effects will be even more effective as trade barriers are removed and all countries allow vaccines to be exported internationally. GOOD TO KNOW: Today 57% of all new medicines globally come from the United States with its world-class IP ecosystem, and private companies in the life sciences community make up more than 80% of the investment in the research and development of those new drugs. The U.S. biopharmaceutical industry directly and indirectly supports over 4 million American jobs. SCIENTISTS, ACADEMICS, ADVOCATES AND POLITICAL LEADERS SKEPTICAL OF WAIVING IP RIGHTS “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WASHINGTON POST EDITORIAL BOARD, May 4, 2021 “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WALL STREET JOURNAL EDITORIAL BOARD, May 6, 2021 “The U.S. decision to support a temporary waiver of intellectual-property protections for Covid-19 vaccines won’t end debate on the issue, much less end the pandemic. Reaching a formal agreement could take months and even then may not accelerate vaccine production; opposition from countries such as Germany could yet doom any compromise.” BLOOMBERG EDITORIAL BOARD, May 12, 2021 “The collaboration that’s happened in the midst of this pandemic I think points to the ways in which IP has actually not been a barrier, but a facilitator of critical, cutting-edge innovation […] I don’t think that waiving IP rights will suddenly enable other countries to ramp up the manufacturing of complex vaccines.” SEN. CHRIS COONS (D-DE), CSIS: April 22, 2021 “There are only so many vaccine manufacturers in the world […] people are very careful about the safety of vaccines […] The thing that is holding us back is not IP. There is no idle factory with regulatory approval that makes magically safe vaccines […] we have all the rights from the vaccine companies and the work is going at full speed” BILL GATES, Sky News: April 25, 2021 “There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” ADAR POONAWALLA, CEO SERUM INSTITUTE OF INDIA, February 14, 2021 “These [vaccines] are complex to make so just waiving IP and patents isn’t going to help […] you can only get trade secrets and knowhow with the cooperation of the originator companies, and they don’t have the bandwidth to do this in every part of the world … the only immediate solution is for rich countries to donate or sell their surplus vaccine to COVAX or other countries.” JAYASHREE WATAL, GEORGETOWN LAW PROFESSOR & FORMER WTO IP COUNSELOR, April 22, 2021 “It is also unclear whether a waiver of IP rights will make a difference […] Furthermore, as others have pointed out, IP rights are only a piece of what is needed to produce vaccines. There is currently a global shortage of raw materials and proper manufacturing facilities.” SAPAN KUMAR, LAW FOUNDATION PROFESSOR OF LAW AT THE UNIVERSITY OF HOUSTON LAW CENTER, May 9, 2021 “This is technology that’s every bit as critical as munitions and encryption codes […] It’s a platform technology that can be used to make all manner of treatments going forward, including vaccines.” DAVID KAPPOS, FORMER U.S. PATENT AND TRADEMARK OFFICE FOR PRESIDENT OBAMA, April 22, 2021 “The notion that we would then turn around and go to the World Trade Organization and basically endorse a policy of DARPA-funded technology transfer to China is just inconceivable. You’re basically aiding and abetting China’s ‘Made in China 2025’ plans for technological dominance.” CLETE WILLEMS, FORMER SPECIAL ASSISTANT TO THE PRESIDENT FOR INTERNATIONAL TRADE, INVESTMENT, AND DEVELOPMENT, April 22, 2021.

**4] Skill Disparities and Trade Secrets – Moderna proves IP isn’t the root cause.**

**Silverman 3-15** Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would **not enforce IP rights** on its coronavirus vaccine — and yet it has **taken no steps to share information** about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the **company’s direct control** within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.