# 1NC Valley RR R5

## Offs

### T

#### Interpretation: The affirmative may not defend patent term extensions.

#### Reduce means make smaller, Cambridge:

<https://dictionary.cambridge.org/us/dictionary/english/reduce> //LHP AV

**to** become or to **make** **something** become **smaller** **in** size, amount, **degree**, importance, etc.:

#### Violation: They use patent term extensions which are the same length. Either a] the extension is extra T or b] they don’t reduce at all because it’s the same length – their ev below

Pandemic-related patent term extensions could be given for a period of time that the compulsory license is in force. With current pandemic projections of six months to two years for sufficient distribution, providing a patent term extension is reasonable and in line with the time period of many patent term extensions. Given that most pharmaceutical patents are prosecuted in multiple countries, this provides an incentive to participate in a limited waiver program.

#### Vote neg:

#### 1] Semantics –

#### A] jurisdiction – you don’t have the jurisdiction as per the tournament invite to vote on nontopical affs – outweighs because it constrains your ballot

#### B] stasis – anything else justifies the aff not talking about the topic – next it’ll be tech sharing, vaccine transfers, or ip extensions because it’s in the topic area which decks neg prep

#### 2] Ground – all NCs and DAs are based on the incentives of long patent terms, so they destroy any comparative disadvantage

#### 3] Preempt normal means args –

#### A] Normal means doesn’t license the aff to be nontopical – find a better solvency advocate

#### B] your own author says it’s a third option and a novel proposal – not normal nor necessary to be topical

### NC

#### Morality only works if we are motivated to follow it. Any external or outside force fails as a way of looking to morality. People making rules to guide or force others to obey will never be a “moral” system, as individuals must have the desire to take an action in order for them to be motivated to take it. Every actual action has to be explained by a belief or desire that the agent has – else they wouldn’t take it

#### Next, every agent takes their ability to act on their ethical system as instrumentally valuable. Only self interest bridges relativism to provide a universal principle.

**Moore** Margaret Moore, Queens University professor in the Political Studies department, cross-appointed (as a courtesy) in Philosophy, Reviewed Work(s): Morals by Agreement. by David Gauthier, Noûs, Vol. 25, No. 5 (Dec., 1991), pp. 707-714 ///AHS PB /BHHS AK recut

On Gauthier's view, morality is a sub-set of self-interest (he calls it preference-fulfillment), which is instrumentally necessary, not absolutely, but given features of the human situation which are almost certain to ob- tain. By taking as his starting-point the agent's subjective motivational set, whatever its content, Gauthier can claim that the requirements of morality escape none who fall under its ambit, for each person necessarily acts on his or her desires and aims. If Gauthier's project is successful, he will have refuted the moral skeptic: by demonstrating that morality is self-interestedly rational, he can claim that the principles are justified and that they apply to everyone. He does not need to presuppose a feeling such as sympathy to explain moral action, or appeal to a process of moral education and socialization within communities which shape the individual's desires and beliefs in accordance with a specific moral conception. Gauthier's agents simply maximize their utility and in the process find that they need to co-operate with others and that the dynamics of co- operation make it rational in self-interested terms to constrain their utility- maximization. By considering in this way the principles and constraints which it would be rational for co-operating self-interested agents to adopt, Gautheir claims to be able to deduce a system of moral constraints and Principles.

#### This entails a system of mutual self restraint: moral principles can be only be the object of a hypothetical moral agreement that all agents have reason to implement. Contracts are the only standard capable of generating normativity since each agent rationally chooses to protect their self-interest by entering the contract.

**Gauthier** [David Gauthier, Canadian-American philosopher best known for his neo-Hobbesian social contract theory of morality, Why Contractarianism?, 1998], ///AHS PB /BHHS AK recut

I shall not rehearse at length an argument that is now familiar to at least some readers, and, in any event, can be found in that book. But let me sketch briefly those features of deliberative rationality that enable it to constrain maximizing choice. The key idea is that in many situations, if each person chooses what, given the choices of the others, would maximize her expected utility, then the outcome will be mutually disadvantageous in comparison with some alternative – everyone could do better**. 14 Equilibrium, which obtains when each person ’ s action is a best response to the others ’ actions, is incompatible with (Pareto-) optimality, which obtains when no one could do better without someone else doing worse. Given the ubiquity of such situations,** each person can see the benefit, to herself, of participating with her fellows in practices requiring each to refrain from the direct endeavor to maximize her own utility, when such mutual restraint is mutually advantageous. No one**,** of course**,** can have reason to accept any unilateral constraint on her maximizing behavior; each benefits from, and only from, the constraint accepted by her fellows. But if one benefits more from a constraint on others than one loses by being constrained oneself, one may have reason to accept a practice requiring everyone, including oneself, to exhibit such a constraint. We may representsuch a practiceas capable of gaining unanimous agreement among rational persons who were choosing the terms on which they would interact with each other. And this agreementis the basis of morality**.** Consider a simple example of a moral practice that would command rational agreement. Suppose each of us were to assist her fellows only when either she could expect to benefit herself from giving assistance, or she took a direct interest in their well-being. Then, in many situations, persons would not give assistance to others, even though the benefit to the recipient would greatly exceed the cost to the giver, because there would be no provision for the giver to share in the benefit. Everyone would then expect to do better were each to give assistance to her fellows, regardless of her own benefit or interest, whenever the cost of assisting was low and the benefit of receiving assistance considerable**.** Each would thereby accept a constraint on the direct pursuit of her own concerns, not unilaterally, but given a like acceptance by others. Reflection leads us to recognize that those who belong to groups whose members adhere to such a practice of mutual assistance enjoy benefits in interaction that are denied to others**.** We may then represent such a practice as rationally acceptable to everyone.This rationale for agreed constraint makes no reference to the content of anyone ’ s preferences**.** The argument depends simply on the structure of interaction, on the way in which each person ’ s endeavor to fulfill her own preferences affects the fulfillment of everyone else**.** Thus, each person ’ s reason to accept a mutually constraining practice is independent of her particular desires, aims and interests, although not, of course, of the fact that she has such concerns**. The idea of a purely rational agent, moved to act by reason alone, is not, I think, an intelligible one.** Morality is not to be understood as a constraint arising from reason alone on the fulfillment of nonrational preferences. Rather, a rational agent is one who acts to achieve the maximal fulfillment of her preferences, and morality is a constraint on the manner in which she acts, arising from the effects of interaction with other agents

#### Thus, the standard is consistency with contractarianism. Prefer for regress – agents can always why a rule exists or how to interpret it – that requires a new rule which is regressive. Thus, only self-imposed contractual obligations can generate normative bindingness

#### I negate –

#### 1] Patents are contracts with the government to protect exclusivity in return for disclosure, WIPO:

WIPO [World Intellectual Property Organization], Frequently Asked Questions: Patents, <https://www.wipo.int/patents/en/faq_patents.html> //LHP AV

What is a patent? **A patent is an exclusive right granted for an invention**. In other words, a patent is an exclusive right to a product or a process that generally provides a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application. **The patent owner may give permission to, or license, other parties to use the invention on mutually agreed terms. The owner may also sell the right to the invention to someone else, who will then become the new owner of the patent**. Once a patent expires, the protection ends, and an invention enters the public domain; that is, anyone can commercially exploit the invention without infringing the patent. What rights does a patent provide? **A patent owner has the right to decide who may – or may not – use the patented invention for the period in which the invention is protected**. In other words, patent protection means that the invention cannot be commercially made, used, distributed, imported, or sold by others without the patent owner's consent. What kinds of inventions can be protected? Patents may be granted for inventions in any field of technology, from an everyday kitchen utensil to a nanotechnology chip. An invention can be a product – such as a chemical compound, or a process, for example – or a process for producing a specific chemical compound. Many products in fact contain a number of inventions. For example, a laptop computer can involve hundreds of inventions, working together. How long does patent protection last? Patent protection is granted for a limited period, generally 20 years from the filing date of the application. Is a patent valid in every country? Patents are territorial rights. In general, the exclusive rights are only applicable in the country or region in which a patent has been filed and granted, in accordance with the law of that country or region. How are patent rights enforced? **Patent rights are usually enforced in a court on the initiative of the right owner**. In most systems a court of law has the authority to stop patent infringement. However the main responsibility for monitoring, identifying, and taking action against infringers of a patent lies with the patent owner. What does it mean to “license a patent” and why is it done? Licensing a patent simply means that the patent owner grants permission to another individual/organization to make, use, sell etc. his/her patented invention. This takes place according to agreed terms and conditions (for example, defining the amount and type of payment to be made by the licensee to the licensor), for a defined purpose, in a defined territory, and for an agreed period of time. A patent owner may grant a license to a third party for many reasons. The patent owner may not have the necessary manufacturing facilities, for example, and therefore opts to allow others to make and sell his/her patented invention in return for “royalty” payments. Alternatively, a patent owner may have manufacturing facilities, but they may not be large enough to cover market demand. In this case, he/she may be interested in licensing the patent to another manufacturer in order to benefit from another income stream. Another possible situation is one in which the patent owner wishes to concentrate on one geographic market; therefore the patent owner may choose to grant a license to another individual/organization, with interests in other geographical markets. Entering into a licensing agreement can help to build a mutually-beneficial business relationship. Unlike selling or transferring a patent to another party, the licensor continue to have property rights over the patented invention. Why are patents useful (to society, business, individuals etc.)? Patented inventions have, in fact, pervaded every aspect of human life, from electric lighting (patents held by Edison and Swan) and plastic (patents held by Baekeland), to ballpoint pens (patents held by Biro), and microprocessors (patents held by Intel, for example). Patents provide incentives to and protection for individuals by offering them recognition for their creativity and the possibility of material reward for their inventions. **At the same time, the obligatory publication of patents and patent applications facilitates the mutually-beneficial spread of new knowledge and accelerates innovation activities by, for example, avoiding the necessity to “re-invent the wheel”.** Once knowledge is publicly available, by its nature, it can be used simultaneously by an unlimited number of persons. While this is, without doubt, perfectly acceptable for public information, it causes a dilemma for the commercialization of technical knowledge. **In the absence of protection of such knowledge, “free-riders” could easily use technical knowledge embedded in inventions without any recognition of the creativity of the inventor or contribution to the investments made by the inventor. As a consequence, inventors would naturally be discouraged to bring new inventions to the market, and tend to keep their commercially valuable inventions secret.** A patent system intends to correct such under-provision of innovative activities by providing innovators with limited exclusive rights, thereby giving the innovators the possibility to receive appropriate returns on their innovative activities. In a wider sense, the public disclosure of the technical knowledge in the patent, and the exclusive right granted by the patent, provide incentives for competitors to search for alternative solutions and to “invent around” the first invention. These incentives and the dissemination of knowledge about new inventions encourage further innovation, which assures that the quality of human life and the well-being of society is continuously enhanced. Applying for patent protection What conditions must be met to obtain patent protection? There are numerous conditions that must be met in order to obtain a patent and it is not possible to compile an exhaustive, universally applicable list. However, some of the key conditions include the following: The invention must show an element of novelty; that is, some new characteristic which is not known in the body of existing knowledge in its technical field. This body of existing knowledge is called “prior art”. The invention must involve an “inventive step” or “non-obvious”, which means that it could not be obviously deduced by a person having ordinary skill in the relevant technical field. The invention must be capable of industrial application, meaning that it must be capable of being used for an industrial or business purpose beyond a mere theoretical phenomenon, or be useful. Its subject matter must be accepted as “patentable” under law. In many countries, scientific theories, aesthetic creations, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, methods for medical treatment (as opposed to medical products) or computer programs are generally not patentable. The invention must be disclosed in an application in a manner sufficiently clear and complete to enable it to be replicated by a person with an ordinary level of skill in the relevant technical field. Who grants patents? **A patent is granted by a national patent office or by a regional office that carries out the task for a number of countries. Currently, the following regional patent offices are in operation:** African Intellectual Property Organization (OAPI) African Regional Intellectual Property Organization (ARIPO) Eurasian Patent Organization (EAPO) European Patent Office (EPO) Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office) Under such regional systems, an applicant requests protection for an invention in one or more member states of the regional organization in question. The regional office accepts these patent applications, which have the same effect as national applications, or grants patents, if all the criteria for the grant of such a regional patent are met. There is currently, no universal, international system for the grant of patents.

#### Impacts –

#### A] Violating contracts agreed to is intrinsically bad as per the framework

#### B] mutual advantage of the contract is undermined as inventors have no incentive to disclose their inventions, which also turns case because other companies can’t make it if they don’t know how to

#### C] Free riding – other agents can use the knowledge without contribution, which violates the framework because agents not involved in the contract unjustifiably exploit another person.

#### 2] Illegitimacy – the conditions that can create a legitimate new contract are not present – thus, the aff is illegitimate

#### A] imbalance of power – the international sphere has certain countries with more power over others, which means the aff can never be justified as a contract – rational parties would never need a contract in a space with power imbalance

#### B] Third Parties – the ones affected are the pharmaceutical companies and their rights, so making a contract absent their consent is illegitimate

## Case

### Solvency

#### [1] The proposed waiver won’t solve because of how complicated it would be to mandate disclosure and transfer of trade secrets—the plan is insufficient to trigger the advantages, Donahoe

<https://www.natlawreview.com/article/waiver-ip-protections-covid-19-vaccines-still-under-consideration-wto>, 24 Aug 2021, Donahoe, Casey D.

While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. Katherine Tai, the U.S. Trade Representative, has not publicly committed to any position beyond waiving patent protections in particular. [Karpan 2021-07-01] Moderna has temporarily waived its COVID-19 vaccine patent rights, but the vaccine is still protected, at least in the U.S. and EU by regulatory marketing exclusivity. [Collins 2021-06-11] **With respect to patents, existing TRIPS flexibilities already allow for countries to issue compulsory licenses for domestic production in the face of public health crises and, under additional criteria, compulsory licenses for export.** But proponents of the waiver argue that the existing processes, which can require country-by-country and case-by-case negotiations and litigation with the vaccine developers and may be limited to public uses, are too time-consuming and inconvenient to mount an effective response, particularly where thickets of IP protection cover single vaccines. [Labonte 2021-01-09, The Conversation]; [Public Citizen, tradewatch.org] In fact, compulsory licensing to exporting manufacturers under Article 31b is has only been successfully used once in the past twenty years, [Public Citizen, tradewatch.org] when Canada issued a compulsory license authorizing the manufacture and export of an AIDS medication to Rwanda. [WTO 2007-10-04] Additionally, multiple countries may be involved in the pipeline for manufacturing a single packaged vaccine to be distributed in a country in need. Further, one key advantage to a unanimously agreed-upon waiver over attempting to utilize existing TRIPS flexibilities, would be that countries could more comfortably exploit the waiver without the threat of trade complaints or sanctions from other nations. [Lopez 2021-05-07] Proponents of the waiver point to alleged U.S. and European retaliatory trade measures against nations that have attempted to use existing TRIPS flexibilities to skirt IP protections. [Public Citizen, tradewatch.org] While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. **However, even if patent protection were not an issue, manufacturing and distribution of the vaccines would remain a substantial obstacle to achieving global immunity.** [Paton 2021-05-07 Bloomberg] **Aspects of vaccine manufacturing and regulation raise further issues of what TRIPS calls “undisclosed information,” encompassing trade secrets and know-how. Such undisclosed information may be particularly crucial in scaling up manufacture in a commercially viable fashion**. [Garrison 2020-12-16]. Article 39 of TRIPS requires members to protect the confidentiality of undisclosed information, including data submitted to regulatory agencies for marketing approval of pharmaceuticals. **As related to vaccines, undisclosed information could include clinical data** (e.g., related to effectivity, including negative results), **manufacturing processes, medical formulas, cell lines, genomic information, technical designs and specifications, instruction manuals, process controls and monitoring, quality control procedures, technical training, working practices, etc.** [Garrison 2020-12-16]; [Levine 2020-07-10]; [Eakin 2021-05-25 Law360] **The Pfizer and Moderna vaccines,** in particular, are expected to be **extremely difficult to replicate** given **they rely on new mRNA technology.** The WTO touts the COVID-19 Clinical Research Coalition, which aims to provide a platform for voluntary data-sharing, and the WHO-backed COVID-19 Technology Access Pool (C-TAP), which provides a platform for technology developers to bundle intellectual property rights, knowledge, and data into non-exclusive licenses with each other and with multiple quality-assured manufacturers, as examples of voluntary efforts to fill-in the know-how gap. [WTO Report 2020-10-15] In general, the voluntary transfer of know-how between two parties is highly contractually stipulated, usually allowing the licensor strict control over the dissemination of its know-how and protecting rights to improvements and developments that may derive from the collaboration, some of which might be patentable in themselves. [Bracho 2021-05-24 Bloomberg]. **The proposed waiver**, though, **wades into relatively unchartered territory of compulsory transfers of undisclosed information. Likely the biggest threat felt by vaccine manufacturers is that the compulsory transfer of undisclosed information will not simply diminish their return on investments in COVID19 vaccines, but would jeopardize entire proprietary technological platforms that support a wide range of potential products.** Such giveaways would likely impact small-to-medium sized enterprises especially, which account for approximately 75% of US COVID-19 treatments, and particularly small university spin-outs, which are highly depend on IP for valuation. [Balfour 2021-06-30] As details of a waiver have not yet been hammered out, it remains unclear exactly who might have access to such undisclosed information (e.g., the general public or only generic manufacturers) and the mechanisms by which such transfers would be achieved. Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. [Labonte 2021-01-09, The Conversation**] The most obvious means would be for regulatory agencies to disclose data and manufacturing protocols submitted by vaccine manufacturers that they are ordinarily required to keep confidential.** In fact, the issue of data confidentiality has already been raised in the U.S. as an obstacle to developing a competitive generic biologics market, with some pointing to the Federal Pesticide Act (FPA) as a successful model which allows more free dissipation of regulatory data by the EPA. [Heled 2019] There are some exemptions to confidentiality of data supplied to regulatory drug agencies implemented in the U.S. and Europe, particularly where public funding helped finance the underlying research. For example, for research funded by the U.S. government, the Bayh-Dole Act provides some additional licensing provisions to the government which could potentially extend to some know-how; however, these provisions are largely untested and may be contractually restricted. [Collins 2021-06-11]. **But there is no precedent for compulsory transfer of confidential information in general**. [Levine 2020-07-10] **Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information.**

**Additionally, knowledge holders may be located outside the jurisdiction of a member state desiring to compel transfer,** [Garrison 2020-12-16] **and waiving an obligation for member states to protect undisclosed information does not necessarily compel other member states to do so.  Notably, India, one of the waiver proponents that actually has substantial pharmaceutical manufacturing capacity, does not even presently require submission of test data for marketing approval.**  [Haugen 2020-12-01]  **Compulsory disclosure of undisclosed information is further complicated by the fact that the knowledge holders for manufacturing a single vaccine may be dispersed across multiple entities and/or even multiple jurisdictions, particularly where a supply chain of highly technical components is utilized or certain processes are outsourced to contractor entities.**  [Garrison 2020-12-16]  **The legislative levers that might be needed to fully enforce compulsory disclosure of undisclosed information or that could be pulled to halt executive branch action, as well as the lawsuits that might be filed would seem likely to stall any grand gestures of governmental action related to undisclosed information.** [Eakin 2021-05-25 Law360]  **For instance, compulsory disclosures would likely spurn allegations of violating the Takings Clause of the Fifth Amendment**, although the Supreme Court had found previously in *Ruckelshaus v. Monsanto Co*. that the FPA had not done so [Heled 2019].  Still, compulsory disclosure facilitated by regulatory agencies may not be sufficient to fill the knowledge gap for the successful manufacture of the vaccines, leaving room for countries to consider other creative avenues.  Brazil, for instance, has proposed one of a kind legislation which would tie patent rights to the compulsory disclosure of all information needed to make COVID-19 vaccines.  [Eakin 2021-05-25 Law360] Opponents argue that **bottlenecks in manufacturing capacity and supplies would stymie the effect of the waiver, despite the transfer of undisclosed information, and that even with full technology transfer, it would take months or years for factories to come up to speed on vaccine production.**  [Leonard 2021-05-06, Bloomberg]; [Paton 2021-05-07 Bloomberg]  **Manufacturing capacity is particularly limited for mRNA-based vaccines and there’s not even necessarily a sufficient population of people with expertise capable of manufacturing them.**  [Karpan 2021-05-11 Law360]  **Some also warn that redistributing crucial supplies to manufacturers without existing capabilities to manufacture the high-quality vaccines with regulatory approval would actually hinder vaccine distribution efforts.**  [Karpan 2021-05-11 Law360]; [Lima 2021-05-08 Bloomberg]; [Paton 2021-05-07 Bloomberg]  Even manufacturing facilities with access to all IP rights are experiencing production delays from regulatory reviews.  [Baschuck 2021-05-06]  Opponents also resound that such efforts to undermine IP rights will only discourage future innovation, including research that targets new variants of the coronavirus.  [Bacchus 2020-12-16 Cato Institute];  [Paton 2021-05-07 Bloomberg] The large divide between fervid proponents of the waiver and even those who have expressed some mild support suggests any significant compromise may be some time coming.  Many view the waiver controversy any way as less of a problem-driven exercise and more of an opportunity for the usual players to debate both the power of big pharma in the U.S.  [Collins 2021-06-11] and the stifling effects IP protections can have on the least developed nations around the world.  Also, the angst amongst some proponents of the waiver, some believe, may stem more from policies of vaccine nationalism than of TRIP impediments. [Clarke 2021-04-22 Lexology] Regardless, the decisions reached at the WTO during this crisis are likely to shape future policy discussions for years to come.

#### [2] Waivers won’t solve the actual problem. Supply will be a non-issue by years end. The TRIPS waiver is a theatrical gesture aiming to let rich economies off the hook for actually solving the problem, Adler

<https://foreignpolicy.com/2021/07/20/wto-trips-waiver-vaccine-equity-distribution-covid-pandemic/>, July 20, 2021

These rollout problems found in the United States are amplified many times when it comes to global rollout. The Biden administration discovered this first hand when it attempted to donate 80 million doses from domestic U.S. supply to the rest of the world in June but fell well short of this target. **White House press secretary Jen Psaki** [**said**](https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/21/press-briefing-by-press-secretary-jen-psaki-june-21-2021/)**, “what we found to be the biggest challenge is not actually the supply—we have plenty of doses to share with the world—but this is a herculean logistical challenge.** And we’ve seen that as we’ve begun to implement.” She pointed to the distributional challenges associated with storing vaccines at the proper temperature as well as the need for needles and syringes. **The TRIPS waiver can be seen as essentially a political or even theatrical gesture.** As Psaki’s comments show, there is more to vaccinating the world than just increasing supply. **Even if there are vaccine shortages at this moment, limited vaccine supply may not be a binding constraint by year end**. Serum Institute of India, the world’s largest vaccine manufacturer, has announced **it will begin** [**exporting later this year**](https://www.reuters.com/world/india/indias-serum-institute-start-export-covid-19-vaccine-by-year-end-2021-05-18/)**, implying India should have adequate vaccine supply by then.** **Pfizer/BioNTech has** [**pledged to deliver**](https://www.voanews.com/covid-19-pandemic/pfizer-biontech-pledge-2-billion-vaccine-doses-poor-nations) **2 billion doses to low- and middle-income countries**. **AstraZeneca is continuing to scale up production.** Nonetheless, the Biden administration’s signature international COVID-19 policy, the [**TRIPS waiver**](https://crsreports.congress.gov/product/pdf/IN/IN11662)**, is a supply side move—but one unlikely to lead to any actual increase in supply**. This waves intellectual property protections for COVID-19 vaccines to further foreign production. The [U.K.](https://www.gov.uk/government/news/wto-trips-council-june-2021-uk-statements) and [German](https://www.dw.com/en/germany-rejects-us-push-to-waive-covid-vaccine-patents/a-57453453) governments have viewed it skeptically and can block it. Also, as has been widely noted, manufacturing involves trade secrets and supply chain issues that go well beyond intellectual property (IP) rights. Less widely noted is the fact that the Johnson & Johnson, AstraZeneca, and Novavax vaccines have already been [licensed to Indian manufacturers](https://www.statnews.com/2021/05/05/india-vaccine-heist-shoddy-regulatory-oversight-imperil-global-vaccine-access/), so it is not clear to what degree IP rights are really hindering additional foreign production. Therefore, the TRIPS waiver can be seen as essentially a political or even theatrical gesture, well removed from the messy world of vaccine distribution and administration. It appealed to a domestic audience hostile to Big Pharma and an international audience of countries like India and South Africa whose industrial policies have long called for limitations on IP rights. The Biden administration’s policies keep [evolving](https://foreignpolicy.com/2021/07/16/biden-africa-covid-19-ship-millions-vaccines/), and newer proposals are likely to show more immediate results. The United States has [pledged](https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/) to buy 500 million U.S. produced doses of the Pfizer/BioNTech vaccine over the next year and donate them to low-income countries. Many [financing initiatives](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort) have been announced. But U.S. plans of how to tackle the critical last mile and get the vaccines into people’s arms have not been as clearly fleshed out, with the United States mostly taking a hands-off approach. Administering vaccines requires a global rollout plan. After all, as the truism goes, a global pandemic demands a global response. However, this phrase is open to interpretation, with vaccine nationalism typically cloaked in globalist rhetoric. Many in the United States are deeply uncomfortable with a U.S.-led pandemic effort and hear the statement to mean that globalist institutions should take the lead. In other countries, the phrase can mean something very different. For instance, when European Commission President Ursula von der Leyen floated the idea of a “[vaccine export transparency mechanism](https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_221)” to block vaccine exports from the EU to the U.K., she said it was for the “global common good.” These various meanings are somehow aligned in discouraging any U.S. unilateralism and pose challenges to a more active U.S. involvement in a global rollout. The primary global initiative to ensure all countries have access to COVID-19 vaccines is [COVAX](https://www.gavi.org/covax-facility?gclid=Cj0KCQjwub-HBhCyARIsAPctr7wD6lbQwpflk8lliN12KxEUIUL9NkbdH7NgZ3UTkYqdsLWgG380utMaAqtvEALw_wcB), co-convened by the Coalition for Epidemic Preparedness Innovations, the vaccine alliance Gavi, and the World Health Organization. Gavi oversees procurement but does not have an [on-the-ground presence](https://www.gavi.org/our-alliance/operating-model) for administering vaccines. This is left up to the health ministries of developing countries and other partners. The coalition’s key partner responsible for delivering vaccines is UNICEF. UNICEF is a [children’s agency](https://www.unicef.org/) whose mission is helping every child thrive all over the world. However, it is the elderly who are most at risk for COVID-19. Ultimately, COVAX has rollout capabilities but limited bandwidth and resources when it comes to vaccine administration. The United States has these resources, including deep expertise in both vaccine distribution and administration. Operation Warp Speed showed the Defense Department can manage the complex ultra-cold logistics required for mRNA vaccine distribution. The Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) have knowledge of vaccine administration—although addressing a global pandemic would be a “stretch goal.” The United States could use its personnel and expertise to help solve the global rollout problem, either on its own or in a partnership with multilateral institutions, such as COVAX. This is not to imply the United States, with its declining life expectancy, necessarily has a better health system than other afflicted countries—only that it has rollout knowledge it learned the hard way. The key lesson is the last mile is the hardest part to roll out. Rather than having vaccine supplies arrive and only then start training, it is better to have mass vaccination sites up and running and already fully staffed. The United States could offer technical guidance and materials necessary for rollouts, including refrigeration, ancillary kits, and having enough needles on hand. USAID could offer advice on how a country could improve its vaccine readiness plan. Addressing vaccine hesitancy is also critical to a successful rollout. The reasons behind vaccine hesitancy are complex and vary by country and population. Hence, responses need to be country specific but will typically require a massive communications effort. Where is the global effort? Where is the global planning for this effort? Tackling these global, last-mile challenges faces huge domestic roadblocks in the United States. It would require making global rollout a top U.S. foreign-policy priority, necessitating the planning, financing, and personnel of something akin to the Marshall Plan. It would be expensive. It involves industrial planning, which still has negative overtones in the United States. Which agency in the U.S. government should coordinate such a plan? The State Department? The Defense Department? The National Institute of Health? The CDC? The White House COVID-19 Response Team? Perhaps the most divisive question is if the United States should lead such an effort or follow the WHO’s directives. But none of this is relevant because there is no domestic political pressure for pursuing such an approach, unlike the TRIPS waiver. This is because nonprofit activism is still primarily focused on [supply](https://www.amnesty.org/en/latest/news/2021/06/g7-support-for-pharma-monopolies-putting-millions-of-lives-at-risk/) and [eliminating vaccine hoarding](https://www.oxfamamerica.org/press/cnn-rich-countries-are-hoarding-covid-19-vaccines-and-leaving-developing-world-behind-peoples-vaccine-alliance-warns/) by rich countries. True global vaccine equity requires a broader definition and effort beyond just manufacturing more supply, namely creating a global rollout plan and deploying the health resources necessary to get shots into people’s arms. The end result is the United States is hesitant to find more concrete ways to get involved with a global rollout beyond just pledging more vaccine supplies or money. It is hesitant to directly intervene to help the worst afflicted poor countries distribute and administer vaccines. And vaccine hesitancy, in whichever form it takes, can be deadly.

#### Turns case – enables rich countries to politically justify not putting additional effort into int. COVID vaccinations.