# R4 Bronx 1N

## 1

#### Interpretation: The aff must defend a permanent reduction of intellectual property

#### Reduce means unconditional and permanent – the aff is a suspension.

Reynolds 59 – Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959, lexis)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway.  [\*\*\*13]  The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency.

#### Violation: Waivers

#### Vote neg:

#### 1] Limits and ground– their model allows affs to defend anything from pandemics to Biden’s presidency— there's no universal DA since it’s impossible to know the timeframe when there won’t be IP— that explodes neg prep and leads to random timeframe of the week affs which makes cutting stable neg links impossible — limits key to reciprocal engagement since they create a caselist for neg prep (innovation, collaboration, econ, ptx: all core neg literature thrown away)

#### TVA – Read any aff that only reduces IP protections for medicines – like trips plus.

#### Drop the debater (a) deter future abuse – empirically confirmed with aprioris and b] dropping the arg is incoherent because it is dropping the aff advocacy so its functionally the same.

#### Fairness – procedural constraint

#### Education – terminal impact to debate and why its funded

#### No RVI’s –

#### (a) creates a chilling effect – aff is dangerous on theory because they get to prep a long counterinterp in the 1ar and then get the 2ar to collapse, weigh, and contextualize - negs would always be disincentives from reading theory against good theory debaters which leads to infinite abuse so it outweighs time skew and

#### (b) they’re illogical - “I’m fair vote for me” doesn’t make any sense - logic comes first on theory since all args need to make sense in order to be evaluable.

#### Competing interpretations –

#### a] reasonability is arbitrary since it relies upon judge opinion which outweighs since it’s terminally unfair – it relies on something completely out of control and

#### b] reasonability collapses into competing interpretations since you need to justify why your brightline is better than competing ones

## 2

#### The roll of the ballot is to vote for the debater who best proves the truth or falsity of the resolution. To clarify, vote aff if I prove the resolution true and vote neg if they prove it false.

#### Text – Dictionary.com defines affirm as to maintain as true Dictionary.com, [https://www.dictionary.com/browse/affirm] And to negate as to deny the existence, evidence, or truth of Dictionary.com, [https://www.dictionary.com/browse/negate] Text first – Text comes first – a) Controls the internal link to fairness since it’s the basis of things like predictability and prep b) Key to jurisdiction since the judge can only endorse what is within their burden. Jurisdiction always comes first, anything else is intervention c) Even if another role of the ballot is better for debate, that is not a reason it ought to be the role of the ballot, just a reason we ought to discuss it.

#### The Meta Ethic is internalism - 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

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#### 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

#### 3] Secrets are good – they are essential parts of contracts formulated by the subject

## 3

#### Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:

David Austin, [an Analyst in CBO’s Microeconomics Studies Division] and Tamara Hayford, [a principal analyst in the Health, Retirement, and Long-Term Analysis Division, Congressional Budget Office] prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis., April 2021, “Research and Development in the Pharmaceutical Industry” <https://www.cbo.gov/publication/57126> //LHP AV DOA: 9/8/21

At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

#### Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:

Stephen Ezell, [vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] and Nigel Cory, [an associate director covering trade policy at the Information Technology and Innovation Foundation. He focuses on cross-border data flows, data governance, intellectual property, and how they each relate to digital trade and the broader digital economy. Cory has provided in-person testimony and written submissions and has published reports and op-eds relating to these issues in the United States, the European Union, Australia, China, India, and New Zealand, among other countries and regions, and he has completed research projects for international bodies such as the Asia Pacific Economic Cooperation and the World Trade Organization.] “The Way Forward for Intellectual Property Internationally” April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> //LHP AV

INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **IPRs Strengthen Innovation** Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that **counties with stronger IP protection have more creative outputs** (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), **even at varying levels of development**.46 **IPR reforms also introduce strong incentives for domestic innovation**. **Sherwood**, using case studies from 18 developing countries, **concluded that poor provision of intellectual property rights deters local innovation and risk-taking**.47 In contrast, **IPR reform has been associated with increased innovative activity, as measured by domestic patent filings**, albeit with some variation across countries and sectors.48 For example, **Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets**.49 **Park** **and Lippoldt also observed that** the provision of adequate protection for **IPRs can help to stimulate local innovation**, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, **local innovators are introduced to technologies** first **through** the technology transfer that takes place in an environment wherein **protection** of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.**52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts**. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

#### Pharma Innovation prevents Extinction – checks new diseases.

**Engelhardt 8**, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for **r**esearch and **d**evelopment **spurs innovation** in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such **innovation is** both **necessary to maintain the human species** in an ever-changing and always dangerous environment in which **new microbial** and other threats may at any time emerge to threaten **human well-being, if not survival** (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

## Case

### FWK

### FWK – Hijack

#### Permissibility Negates –

#### 1] Semantics – Ought is defined as expressing obligation which means absent a proactive obligation you vote neg since there’s a trichotomy between prohibition, obligation, and permissibility and proving one disproves the other two.

#### Presume neg- A. We assume statements to be false until proven true. That is why we don’t believe in alternate realities or conspiracy theories. The lack of a reason something is false does not me it is assumed to be true.

#### Util collapses to egoism – Solipsism is true – one can only verify self-consciousness since verification relies on our experience of consciousness which we can only do from our own consciousness because we inherently know it exists. However, I cannot verify the existence of others since I cannot go inside or explore their consciousness. Thus, util can only account for my own pleasure and cannot generate a normative reason to care about anyone else’s, which means the only obligation is to maximize my own pleasure.

#### That negates – a) aggregation is impossible by states since it assumes the ability to verify another agent exists b) there’s no obligation under util since there’s no reason care about anyone else’s pain or pleasure and the subject can do whatever it wants.

### FWK – OV

#### [1] Reject Consequentialism – [a] infinite consequences – [

### Advantage

#### [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.

#### [3] Turn- Waiving patents can’t resolve drug access issues but instead create a more dangerous scenario for developing countries – Garde 21

Damian Garde (national biotech reporter for STAT), Helen Branswell (senior writer at STAT covering infectious diseases and global health; former CDC Knight Fellow and Nieman Global Health Fellow at Harvard; recipient of the 2020 George Polk Award for coverage of the Covid pandemic), and Matthew Herper (senior writer at STAT covering medicine). “Waiver of patent rights on Covid‐19 vaccines, in near term, may be more symbolic than substantive.” Stat News. 6 May 2021. JDN. https://www.statnews.com/2021/05/06/waiver‐of‐patent‐rights‐on‐covid‐19‐vaccines‐ in‐near‐term‐may‐be‐more‐symbolic‐than‐substantive/

In October, **Moderna vowed not to enforce its Covid‐19‐related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines**. “There are currently no generic vaccines primarily because there are hundreds of pro‐ cess steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, **but the transfer of skills is not that simple,” said Norman Baylor,** who formerly **headed the F**ood and **D**rug **A**dministration**’s Office of Vaccines Research and Review**, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — **using messenger RNA technology** — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. **There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instanc**e, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in‐demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry‐wide ... looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly **all of the peo‐ ple who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing**.”  As Michelle McMurry‐Heath, CEO of the trade group BIO, put it in a statement, “**hand‐ ing needy countries a recipe book without the ingredients, safeguards, and sizable work‐ force needed will not help people waiting for the vaccine.”**