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#### Interpretation: Topical Affirmatives must defend the reduction of intellectual property protections for all medicines

#### Violation: they spec covid medicines

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It’s applicable to “Medicines” – adding “generally” to the res doesn’t substantially change its meaning because the res never specified further

#### Vote negative

#### 1] limits & ground– the aff can specify any medicine and explode the link scenario – cancer, marijuana, COVID, influenza, common cold - it’s uniquely bad because there’s no term of art like “substantial” in the res which explodes limits. Different affs bracket out different DAs and specific frontlines beat neg generics every time – that sidelines clash and pushes to the margins of the topic

#### 2] TVA – read whole res or specify states without medicines - everyone has generic impact defense on various regions and there are only so many legitimate scenarios but medicine prep is constrained by topic duration

#### Competing interps – you can’t be reasonably topical – it’s a binary question

#### No RVIs – T’s a stock issue, not a reason you should win

#### Reject the team – anything else servers out of plan text which is a voter because it moots the NC

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#### Counterplan: The member states of the World Trade Organization ought to

* **offer generous payment per immunization in LMICs and subsidies to oversee distribution of medicines relating to COVID-19 to local pharmaceutical companies**
* **make rewards conditional upon speed and inoculation efficacy**
* **create IPTK banks to bypass trade secrets and encourage public-private collaboration**

#### Subsidized reward mechanisms harness market demand

**Karan et al 4/2**, Abraar Karan is an internal medicine physician at the Brigham and Women’s Hospital/Harvard Medical School and a columnist at The BMJ. He previously worked on the covid-19 response in Massachusetts state. The views expressed here are his own and do not represent those of his employers, Thomas Pogge is a professor and director of the Global Justice Program at Yale University. He co-founded Incentives for Global Health, a team effort toward creating the Health Impact Fund , 4-2-2021, "Solving global vaccine inequity requires new incentives for pharmaceutical companies,", The British Medical Journal <https://blogs.bmj.com/bmj/2021/04/02/solving-global-vaccine-inequity-requires-new-incentives-for-pharmaceutical-companies/> ]AAli

Scientists have been successful in bringing several highly effective covid-19 vaccines to market in record time. But manufacturing scale-up is slow—with a few companies holding the “know-how,” but unenthusiastic about licensing this to others. Current trends predict that 90% of people in 67 low income countries will not be vaccinated this year and that most poorer populations will not gain herd immunity even in 2022. This delay will facilitate the emergence of new disease strains that may endanger even those already vaccinated. More importantly, millions of people in poor countries will needlessly die, particularly those who are at higher risk of mortality, such as those who are older and immunocompromised. To speed up manufacturing, some 119 developing countries have called for a temporary suspension of intellectual property rights related to covid-19 to allow manufacturers worldwide to produce and sell approved vaccines without the patentee’s permission. Patentees and the affluent countries representing them have opposed such a waiver: it would undermine incentives to innovate against future pandemics, they say, and it would not help much because patentees would not share crucial technologies and know-how with manufacturers who had not paid them for a license to produce and sell (as was the case with Moderna, which liberalized its intellectual property, but little else). And there is a further problem: even with generic manufacturers in the driver’s seat, the world’s poorest populations are still very poor, and thus would still be served last, if ever. Ultimately, waiving global policy agreements like TRIPS is a stopgap measure; the system needs more fundamental change. The urgent needs of the world’s poorest people must be subsidized into effective market demand. This might be done through a massive increase in funding for the existing COVAX facility, which is currently projected to provide two billion doses per year, at best only around 20% of global vaccine needs. COVAX could then offer a generous payment per immunization to pharma companies, featuring a declining premium for early delivery and payment adjustment with regard to quality (for example, how much protection an immunization affords, for how long, against which variants). Such a pay for performance scheme would give firms with approved vaccines a financial incentive to ramp up production for fast delivery. To this end, they would, competing with one another, seek to engage and expand available manufacturing capacity while fully supporting contracted manufacturers. Supplies produced would be directed to where they can be most effective in suppressing the pandemic, without consideration for the poverty or affluence of the various populations. Even if such an initiative were to raise cost by a factor of 10—from the $6 billion COVAX currently has to $60 billion— this would still be a tiny fraction of the economic harm this pandemic has caused and might yet cause in the future. The US alone has just allocated $1.9 trillion to avert some of the economic damage it has sustained from covid-19. An extra $54 billion, spread over many countries, is a small price to pay for bringing this pandemic under control at least two years sooner. A key lesson of covid-19 is that the great benefits the pharmaceutical sector has to offer must fully include the world’s poorest people. This is a firm command of justice and, at least with communicable diseases, an imperative of prudence as well. We must place advanced pharmaceuticals within reach of poor communities and must ensure that the diseases concentrated among them are lucrative targets of pharmaceutical research and development. To achieve global pharmaceutical equity in a sustainable way, we should create a complementary reward mechanism, additional to patent monopolies, that is designed to pay for better health outcomes. This mechanism can be but is not limited to the Health Impact Fund (a system one of us, TP, co-founded), which gives innovators the option to have any of their new pharmaceuticals rewarded according to the health gains achieved with it, on condition that it is sold at the variable cost of supplying it. Here “health gains” would be understood to cover not merely the therapeutic improvements that users experience, but also wider societal benefits, such as reduced infections among non-users. Moreover, pharmaceutical companies would be incentivized to effectively oversee and coordinate the delivery of therapeutics to end users, whether that be through national health systems or public-private partnerships. As an immediate example, such a system could effectively benefit latecomers to vaccine rollouts, given that there is an immense market potential remaining in low and middle income countries, which is largely uninteresting to early comers like Moderna and Pfizer whose supply has already been sold to high income countries. With the Health Impact Fund in place, the global pharmaceutical sector would be much better prepared to respond effectively to future pandemics, and would have been for past ones too (we wrote about this in the context of the Ebola and Zika viruses previously). Furthermore, it would be able to profitably unleash its skills upon the enormously harmful diseases associated with poverty, including the 20 WHO listed neglected tropical diseases, which affect over a billion people, as well as tuberculosis, malaria, hepatitis, and pneumonia, which together kill millions of people each year. We can and must tackle these diseases. The investment for doing so would pay for itself many times over.

#### IPTK banks are key to DCVMs

**Crager 18** [Dr. Sara Crager, MD is a board certified emergency medicine physician in Los Angeles, California. She is affiliated with Ronald Reagan UCLA Medical Center, 2018 December, "Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6291766/> ]//AAli

\*developing country vaccine manufacturers

I propose a strategy that would integrate key aspects of both these models, creating a structure capable of facilitating access to new vaccines by establishing an entity that pools all relevant intellectual property, technology, and know-how: an IPTK bank. An IPTK bank would bring together the necessary intellectual property rights, manufacturing process information, know-how, and regulatory expertise into a single platform that could be licensed as a package with associated training modules; it could also offer assistance in navigating vaccine registration with national regulatory authorities. A licensing approach similar to that used by the MPP would be employed to address intellectual property barriers by creating a structure whereby the patented technology could be disseminated to multiple DCVMs, each paying royalties to the patent holder. The manufacturing process information, know-how, and regulatory expertise would be brought together through the organization hosting the IPTK bank, which would closely mirror the organizational model of the WHO technology transfer hub. Barriers to Creation of the Proposed Banks Funding, inevitably, will be a major barrier to the creation of IPTK banks. IPTK banks would require an initial period of funding in order to acquire and then disseminate the vaccine technology. Once a critical mass of DVCMs began producing the vaccine, however, provision of affordable vaccines would be self-sustaining, with reliance on market forces to ensure appropriate price declines. IPTK banks thus would not be as subject to the vagaries of sustained donor funding as organizations like GAVI, but would rather need to raise enough money to support the initial acquisition and dispersal period for each new vaccine technology. Given that projected spending on new vaccines necessary to achieve the GVAP goals is estimated at nearly US $30 billion, it may ultimately be more cost-effective to invest in upstream mechanisms to rapidly achieve sustained price reductions for new vaccines. The greatest barrier to the creation of IPTK banks is the need for close cooperation with innovator companies. Fundamentally, engaging with an IPTK bank would be similar to the technology transfer arrangements that multinational pharmaceutical companies frequently enter into with individual DCVMs to expand their regional vaccine production and distribution. The major departures from a traditional technology transfer agreement would include licensing terms that allow the IPTK bank to grant nonexclusive licenses to multiple DCVMs and the transfer of technology to a hub organization at a publicly funded institution rather than directly to a DCVM. Because an IPTK bank strategy depends on significant involvement from innovator companies, creating appropriate conditions that incentivize their participation is key to the success of this model. Engagement With Innovator Companies Multinational pharmaceutical companies frequently engage in successful technology transfer with DCVMs, and this trend appears to be growing. According to an International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) spokesperson, Technology transfer in medicines and vaccines were growing rapidly in the past decade, benefiting both pharmaceutical companies and the health of recipient countries’ population alike.51 In fact, so much interest has developed around this topic that the IFPMA recently issued a research paper titled “Technology Transfer: a Collaborative Approach to Improve Global Health—the R&D Pharmaceutical Industry Experience.” In addition to providing numerous case studies of technology transfer partnerships, the paper identified 8 conditions that the pharmaceutical industry considers necessary for successful technology transfer relationships: a viable and accessible local market, political stability and good economic governance, clear economic development priorities, adherence to high regulatory standards, availability of skilled workers, adequate capital markets, strong intellectual property rights and effective enforcement, and a high-quality relationship between industry and government, and their ability to work together effectively for long periods of time. An IPTK bank as a technology partner would fulfill most of these criteria. The fact that an IPTK bank would almost certainly be based in a high-income country would also address a number of these issues. In this context, there should be relatively little concern over issues such as political stability and good economic governance, and most industrialized-country governments are generally considered to have relatively good relationships with industry and a long history of working together effectively. These conditions may not be guaranteed to the same degree in all countries that receive technology from an IPTK bank, but that risk would not be directly borne by the company and would be distributed over multiple potential technology partners. In addition, high-income countries generally have well-established systems of strong intellectual property rights with effective enforcement. Again, this may or may not be true to the same extent in all countries that are recipients of IPTK bank technology; however, industry has already shown itself willing to discuss licensing arrangements with the MPP that would involve licensing intellectual property rights to a central organization, which would then provide nonexclusive licenses to multiple other entities in countries that may not have similarly strong enforcement of intellectual property rights. Regarding access to viable local markets, although the IPTK bank itself would not directly have such access, licenses would be granted only to partners with demonstrable access to local markets large enough to achieve economies of scale such that significant price reductions could be generated (as occurs with the MPP). Finally, if the IPTK bank is based at an institution such as the Netherlands Vaccine Institute or the International Vaccine Institute, availability of skilled workers should be more than adequate. Basing the IPTK bank within such organizations would provide a strong base of experience in adherence to high regulatory standards that would be passed on to IPTK bank technology recipients. Overall, IPTK banks would fulfill the criteria that the IFPMA has identified as being critical to the decision of multinational pharmaceutical companies to engage with a technology transfer partner. The major departure from the technology transfer arrangements described in the IFPMA report would be use of a licensing covering all necessary intellectual property modeled on the MPP licenses rather than the traditional sublicense negotiated between pharmaceutical companies and their technology partners. Companies have demonstrated their willingness to enter into negotiations involving such licenses with the MPP, providing a precedent that this may not present an insurmountable barrier to companies engaging in technology transfer agreements with an IPTK bank. Although an IPTK bank would require a high degree of commitment and cooperation from innovator companies, it seems possible that industry might be willing to consider engaging in discussion regarding this approach to expanding vaccine access.

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#### Counterplan: The member states of the World Trade Organization ought to

* **adopt the Multiparty Interim Appeal Arbitration Arrangement**
* **grant the United States Federal Government the ability to nominate four of ten appointees**
* **agree to temporarily use the MIAAA to resolve existing WTO disputes and reevaluate the dispute settlement mechanism’s status every 6 months**

Simon **Lester** was the associate director of Cato’s Herbert A. Stiefel Center for Trade Policy Studies. His research focused on World Trade Organization disputes, regional trade agreements, disguised protectionism, and the history of international trade law., **9-1**-2020, "Can Interim Appeal Arbitration Preserve the WTO Dispute System?," Cato Institute, <https://www.cato.org/free-trade-bulletin/can-interim-appeal-arbitration-preserve-wto-dispute-system> ]//AAli

Opinions will vary on the merits of each of these concerns, but regardless, the Trump administration has used these objections as the basis for refusing to go forward with appointments to the Appellate Body, and as a result the Appellate Body is down to one member and no longer functioning. WTO members have attempted to respond to these concerns as part of an effort led by New Zealand ambassador David Walker (the so‐​called Walker Process), but the principles they have developed have not been able to assuage the Trump administration.10 That leaves WTO dispute settlement in an uncertain place. If there is a right of appeal, as there is under the DSU, but no Appellate Body to hear the appeal, a party that loses a complaint brought against it can effectively block a panel report by appealing into the void.11 Does that mean the system has, for practical purposes, returned to its form under the GATT? Or, instead, will parties to disputes refrain from appealing and apply the principle of automatic adoption to WTO panel reports?12 That would be an improvement on the situation under the GATT, although it could lead to incoherence in the jurisprudence if different panels interpret core WTO principles differently. The fundamental question is the following: What exactly will happen to the WTO dispute settlement process without an Appellate Body? The MPIA as a Temporary Replacement for Appellate Review In response to these concerns, the European Union has led an effort to use the general arbitration mechanism in Article 25 of the DSU as the basis for an appeal. Inspired by a 2017 paper from a group of experienced WTO lawyers, the EU initiative has now been joined by 22 other WTO members and is known as the Multiparty Interim Appeal Arbitration Arrangement Pursuant to Article 25 of the DSU.13 MPIA appeals are only available to parties to the MPIA, but other WTO members may join the MPIA at any time.14 The MPIA establishes a standing pool of 10 arbitrators to hear appeals of WTO panel reports. As with the Appellate Body, three arbitrators hear the appeal in a specific case. There is also a parallel to the collegiality that exists at the Appellate Body, under which the three serving arbitrators may discuss each case with the full standing pool of arbitrators.15 The pool of arbitrators has now been selected.16 All 10 MPIA arbitrators have extensive experience working on WTO disputes, with many of them having served as panelists or arbitrators or in the WTO Secretariat divisions that assist panels and the Appellate Body.17 The experience of these arbitrators with WTO disputes, combined with their awareness of the circumstances of the MPIA’s creation, could affect how the MPIA treats the work of the panels they are reviewing. For example, the Appellate Body tended to rewrite the reasoning of panels even where it agreed with the result. Perhaps the MPIA will defer a bit more to panels, offering more limited reasoning when it seems appropriate. The MPIA’s reliance on Article 25 of the DSU, which offers little in the way of guidance, to recreate the appellate review process could lead to other key differences from the Appellate Body. One of the most noteworthy of these is that with the MPIA, its awards will be notified to the WTO’s Dispute Settlement Body but not formally adopted by it. (Nevertheless, the awards will be binding on the parties, as the MPIA states: “The parties agree to abide by the arbitration award, which shall be final.”18) The implications of this for the value of MPIA awards as precedent is uncertain. Presumably, without formal adoption by the WTO membership, there will be some lesser degree of precedential value for these awards, but how much is unclear. The approach to the use of legal and administrative support staff by MPIA arbitrators is also uncertain, with the MPIA text somewhat vague on the issue.19 In WTO disputes, specific divisions of the Secretariat have assisted panels and the Appellate Body, performing the role that law clerks play in domestic legal systems. The Legal Affairs Division and Rules Division took the lead on assisting panels while the Appellate Body had its own dedicated secretariat, which was disbanded and its staff distributed to other WTO divisions after the Appellate Body stopped functioning. Will the former staff of the Appellate Body Secretariat be partially or fully reconstituted to play the same role with the MPIA? Or will the MPIA hire assistants to work only on specific cases? The arbitrators are going to need some sort of assistance, and the form that it takes could help shape the culture and role of the MPIA. A permanent group of staffers who frequently work together could play a role that is different from that of a shifting group of ad hoc assistants. Staff from the WTO could provide this assistance, but there have been early indications that the United States would object to this, so the MPIA parties may have to provide funding for this assistance on their own, independently of the WTO.20 In terms of substantive law, the MPIA has an innovation that will perhaps address the U.S. concern about the consideration of facts in appeals under DSU Article 11. The MPIA provides that “arbitrators may … propose … an exclusion of claims based on the alleged lack of an objective assessment of the facts pursuant to Article 11 of the DSU,” though it notes that such a proposal “is not legally binding and it will be up to the party concerned to agree with the proposed substantive measures.”21 Thus, under this provision, if the MPIA arbitrators choose to do so, they can try to limit the use of Article 11 as a means of addressing factual issues on appeal. Just as there was uncertainty about the Appellate Body in 1995, there is uncertainty about the MPIA now. In addition to the points noted above, there are other questions: What approach will the MPIA take regarding the interpretation of core WTO principles such as the nondiscrimination obligation and public policy exceptions? How often will the MPIA appeal process be used? What kind of legal culture will develop around it, including the approach of the arbitrators and of the litigants themselves? How much deference will the MPIA show toward politically sensitive domestic laws and regulations? How much deference will the MPIA show toward the findings and reasoning of WTO panels? Will the MPIA avoid novel and controversial issues that are put before it or take them on? Only practical experience will give us clear answers. The first practical experience may come from several ongoing WTO disputes for which the parties have agreed to procedures for using the MPIA.22 The dispute that may provide the first opportunity for the MPIA to hear an appeal was brought by Australia against Canadian measures that affect the sale of wine. The arbitrators who hear the early cases will have an opportunity to set the tone with high‐​quality work that satisfies the parties to the MPIA and perhaps gains favor with other WTO members.

#### Normal means is through dispute settlement

**WTO 2** "The process — Stages in a typical WTO dispute settlement case," WTO, <https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c6s1p1_e.htm> ]//AAli

This chapter explains all the various stages through which a dispute can pass in the (WTO) dispute settlement system. There are two main ways to settle a dispute once a complaint has been filed in the WTO: (i) the parties find a mutually agreed solution, particularly during the phase of bilateral consultations; and (ii) through adjudication, including the subsequent implementation of the panel and Appellate Body reports, which are binding upon the parties once adopted by the DSB. There are three main stages to the WTO dispute settlement process: (i) consultations between the parties; (ii) adjudication by panels and, if applicable, by the Appellate Body; and (iii) the implementation of the ruling, which includes the possibility of countermeasures in the event of failure by the losing party to implement the ruling.

#### The WTO appellate body is hamstrung by Trump and Biden – that kills their dispute settlement mechanism

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On February 5, two weeks after his inauguration, President Joe Biden marked the US’ return to multilateralism by lifting opposition to the appointment of Nigeria’s Ngozi Okonjo-Iweala as the new director general of the WTO. Breaking this impasse, in place since October when the Office of the US Trade Representative (USTR) – then led by Robert Lighthizer – threw its support behind Korean Trade Minister Yoo Myung-hee instead, was a major step. “Without the recent swift action by the Biden-Harris administration to join the consensus of the membership on my candidacy, we would not be here today,” said Okonjo-Iweala recently. “I am grateful to the US for the prompt action and strong expression of support.” With a director general in place, all eyes turned to the monthly WTO dispute settlement body meeting on February 22, with hopes high that the Biden administration would take the lead in reversing the Trump administration-imposed logjam there. “The WTO no longer guarantees access to a binding, two-tier, independent and impartial resolution of trade disputes. This is in clear breach of the WTO agreements,” said the EU in a statement at the meeting. The WTO’s appellate body has been without the quorum necessary to hear appeals since the Trump administration, insisting that that it had outstepped its mandate, blocked the appointment of new nominees in December 2019 – effectively cutting off its ability to resolve international trade disputes. “As we have said so many times, WTO members have a shared responsibility to resolve this issue as soon as possible, and to fill the outstanding vacancies as required by Article 17.2 of the dispute settlement understanding,” the EU statement said. “The EU renews its call on all WTO members to engage in a constructive discussion so that the vacancies can be filled as soon as possible.” Much to the chagrin of onlookers, the US’ response was negative. In response to a slate of proposed appellate body appointments, the US said in a statement that it was “not in a position” to support the decision, adding: “The United States continues to have systemic concerns with the appellate body. As members know, the United States has raised and explained its systemic concerns for more than 16 years and across multiple US administrations.” Speaking to GTR, Andrew Shoyer, partner at law firm Sidley Austin, says: “The interregnum without a functioning appellate body is clearly perceived as a tremendous hole in the WTO, however I don’t believe – as maybe the European Commission was hoping – that this administration as a sort of peace offering will join consensus on the seven members of the appellate body, get the appellate body up and running, and then negotiate solutions on these other concerns about dispute settlement.” The lawyer, who spent seven years at the USTR, serving most recently as legal adviser in the US Mission to the WTO in Geneva, was the principal negotiator for the US of the rules implementing the WTO dispute settlement understanding and has briefed and argued numerous WTO cases before dispute settlement panels and the WTO appellate body. “I think this administration wants to engage in a serious negotiation to address reforms and dispute settlement, and we won’t see consensus on the appellate body until we get those reforms done,” he adds. Although a full return to a pre-Trump trade policy now seems unlikely, the Biden administration is seen as being willing to return the US to its historic leadership role in WTO matters. “There is very much a reason for hope that this administration will want to re-engage seriously and that we will see real progress,” says Shoyer. “The real progress for the US economy would be made in rebuilding and moving multilateral commitments forward. The dispute settlement mechanism is an important piece of that, but I don’t see it as a burning issue for the US right now in light of the administration’s priority on climate policy. Getting the director general in place is enough probably to serve those needs right now.” Katherine Tai, Biden’s pick for the USTR, will likely be at least somewhat less combative than her predecessor, who was particularly perturbed by what he characterised as a series of unfair appellate body rulings against the US. “No one’s really missed [the appellate body] at all,” Lighthizer said at the Milken Institute’s 2020 Asia Summit in December last year. “It’s like there’s this mythology out there that it is needed.” However, in her confirmation hearing, held last week, Tai showed little sign of moving away from the Trump-era stance on the dispute settlement mechanism. “Over the years, the appellate body has overstepped its authority and erred in interpreting WTO agreements in a number of cases, to the detriment of the United States and other WTO members,” she said, in response to a question on the reforms she believes are necessary to ensure the appellate body operates as intended. “In addition, the appellate body has failed to follow existing rules created to ensure that disputes are resolved in a timely manner. Reforms are needed to ensure that the underlying causes of such problems do not resurface and that the appellate body does not diminish the rights and obligations of WTO members.” Nonetheless, Tai does appear to intend to take a more conciliatory approach. “Katherine is very measured,” says Shoyer. “She has seen the limitations of enforcement in the WTO when she led USTR’s China enforcement office.” At her confirmation hearing, she said that she will work in a “practical and constructive” manner to re-engage with “like-minded partners” as well as collaborating closely with Okonjo-Iweala. Upon her appointment – which still requires Senate confirmation – Tai will have a tough job ahead of her in tackling the myriad challenges miring the relationship between the world’s largest trading nation and the world’s only multilateral trade body. While the US’ much-feted return to multilateralism under the Biden administration gathers pace, the WTO’s dysfunctional dispute settlement mechanism might take longer to recover.

#### There is literally nobody on the review board – all their terms have expired

**WTO, 11-30**-2020, "Dispute settlement," WTO, <https://www.wto.org/english/tratop_e/dispu_e/appellate_body_e.htm> ]//AAli

The Appellate Body was established in 1995 under Article 17 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU). It is a standing body of seven persons that hears appeals from reports issued by panels in disputes brought by WTO Members. The Appellate Body can uphold, modify or reverse the legal findings and conclusions of a panel, and Appellate Body Reports are adopted by the Dispute Settlement Body (DSB) unless all members decide not to do so. The Appellate Body has its seat in Geneva, Switzerland. Currently, the Appellate Body is unable to review appeals given its ongoing vacancies. The term of the last sitting Appellate Body member expired on 30 November 2020.

#### Solves WTO cred – your evidence agrees [Mitty reads yellow]

Solís 20. [(Mireya Solís is director of the Center for East Asia Policy Studies, Philip Knight Chair in Japan Studies, and a senior fellow in the Foreign Policy program at Brookings. “The post COVID-19 world: Economic nationalism triumphant?” July 10, 2020. <https://www.brookings.edu/blog/order-from-chaos/2020/07/10/the-post-covid-19-world-economic-nationalism-triumphant/>] TDI // rhgt AAli

The damage caused by the worst global health crisis in a century is vast. The new coronavirus has traveled far and fast, infecting more than 8.7 million people and killing more than 460,000. One after another, economies have gone into lockdown to slow down the spread of the disease. The combined supply and demand shocks have ravaged the world economy with the most severe downturn since the Great Depression; **anticipated drops to international trade and investment flows of 30% and 40%,** respectively; and unemployment spikes in many countries. The pandemic has cost lives and livelihoods and has erased the chances of returning to the status quo ante, but it has also brought little clarity regarding what kind of international order it will usher in. Is the future one of deglobalization, decoupling, and reshoring of economic activity? **The pandemic hit an already wounded multilateral trading system**. The chances that the World Trade Organization (WTO) can deliver a multilateral round of trade negotiations to slash tariffs across the board and update the trade and investment rulebook are nil. But the WTO has also lost its central role as arbiter of trade disputes among its members. In December 2019, the Appellate Body ceased to function due to the U.S. block of new appointments, citing judicial overreach. **At a time of rising protectionism, the erosion of a rules-based mechanism to adjudicate disputes bodes ill.** **Longstanding challenges to the WTO have been exacerbated by an abdication of leadership from the great powers to ensure its survival**. China has been the godchild of globalization, leveraging its accession to the WTO to become workshop for the world and a huge domestic market coveted by foreign firms. But China lost its appetite for economic reform, reinvesting on a state capitalism model that imposes heavy costs on other nations. Unchecked subsidies and privileges awarded to its state-owned enterprises, insufficient protection of intellectual property, foreign investment restrictions, forced technology transfers, and cyber protectionism all make the Chinese government’s self-proclamation as champion of global free trade ring hollow. The Trump administration judges the WTO incapable of tackling the China challenge, but instead of creating coalitions of like-minded countries to bring about effective multilateral trade governance, it appears determined to further harm ~~cripple~~ the international organization. It has offered no blueprint to fix the dispute settlement mechanism, has abused the national security exemption to raise tariffs against allies, and is gearing up for its most fundamental assault to date on the WTO: a tariff reset through which the U.S. may unilaterally abandon its commitments on bound tariffs and apply larger duties to force other countries to open their markets. **Trade spats as other countries retaliate in kind is a more likely result.** Tariff wars and the battle for technology supremacy have come to define U.S.-China great power competition. After a grueling trade conflict, the United States and China reached a limited trade agreement in January 2020. The deal marked a pause in the tariff war and addressed some non-tariff barriers on foreign direct investment and intellectual property; but it left intact the core of Chinese industrial policy (public subsidies and state-owned enterprises) and retained U.S. duties on $360 billion worth of Chinese products. China’s massive purchase commitments ($200 billion) were quickly rendered unattainable by the severe economic downturn in China due to COVID-19. In fighting for the new economic order, setting standards on cutting-edge technologies will be at the forefront. China is using all the levers of industrial policy to gain technological primacy in areas like AI and quantum computing. Telecom and the battle over 5G offer a preview of quarrels to come. Deeply concerned with the cybersecurity risks that Chinese telecom giants like Huawei pose, the U.S. government placed the company on its Entity List, banning American exports without a license. It has since tightened the restrictions by barring foreign companies from supplying Huawei with products manufactured with American equipment and technology. National security concerns are increasingly encroaching on existing webs of economic interdependence. Wary of China’s acquisition of critical technology, countries like the United States, Australia, and Japan have tightened their screening of foreign direct investment. The pandemic has only exacerbated concerns that weakened companies in strategic sectors are at risk of foreign takeover. COVID-19’s impact on the international trading system is twofold. It has reinforced existing trends such as the deceleration and now drop in the volume of international trade, the rise of economic security as governments expand their toolkit to restrict trade and investment flows, and it has laid bare the fallout in U.S.-China relations. But the pandemic also brought new challenges that exposed the extent to which trade cooperation is in short supply. Export protectionism has risen in prominence with national restrictions on shipments of essential medical supplies and personal protective equipment. The WTO allows for such curbs for public health purposes – provided the measures are temporary and transparent. Few countries, however, have bothered to comply with their notification commitments. **The blow comes at a time when the WTO is adrift** with the decision of Director General Roberto Azevedo to step down early, opening the search for new leadership in a climate of divisiveness. Graph detailing the number of countries that imposed export restrictions on various categories of medical supplies and devices in response to the coronavirus pandemic. Are we on the eve of a renationalized world economy? That is the aspiration of several American and European public officials who fault extended global supply chains and overdependence on China for the current mishaps in tackling the pandemic. But the view that economic nationalism and reshoring of manufacturing is a fail-safe path to security and prosperity is wrong. For one, it skirts the responsibility of governments to properly stockpile essential medical supplies. Furthermore, the export curbs will be counterproductive, eliminating incentives for producers to expand capacity and increasing the cost of much needed medicines and medical devices. If the recent lockdowns have taught us anything, it is that exclusive reliance on the domestic market is too risky. Diversification of supply, redundancies in the manufacturing chain, and stockpiling programs are better alternatives. In this endeavor, global supply chains are part of the solution, not the problem. COVID-19 will not produce an exodus of foreign companies from the Chinese market. Recent surveys of American companies with operations in China show that most firms intend to stay put. A February survey of Japanese companies conducted by Tokyo Shoko Research shows that only a fraction (4%) are considering exit from China. Therefore, the Japanese government’s $2.2 billion fund to restructure supply chains should be understood as risk management, not decoupling. When international companies map out their business strategies, they must factor in heightened risks – protectionism, national security controls, and economic lockdowns. **Hence, efforts by middle powers to offer an interim arbitration mechanism at the WTO** to handle trade disputes and to commit to maintaining open supply chains in essential medical goods **are the right antidote to rising economic nationalism**. As a staunch supporter of rules-based trade and with its decision to forego export protectionism in the current crisis, Japan has much to contribute to these efforts.

## Off

#### Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) “As Washington Ties Pharma’s Hands, China Is Leaping Ahead” Barron’s Magazine: Commentary, China., 6/11/2021] RM

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, [47% of all new medicines](https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf) were invented by U.S. biopharma companies, with [homegrown startups](https://www.cbo.gov/publication/57126) driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market.

An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from [$1 billion to over $200 billion](https://www.bloomberg.com/news/articles/2021-03-01/xi-mobilizes-china-for-tech-revolution-to-cut-dependence-on-west). China saw over [$28 billion](https://www.bioworld.com/articles/506978-china-sees-five-year-highs-in-life-sciences-investments-and-partnering) invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast.

In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies.

The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in [contravention](https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail) of international standards, and the U.S. national security community believes China is [pushing ahead](https://www.nbcnews.com/politics/national-security/china-has-done-human-testing-create-biologically-enhanced-super-soldiers-n1249914) with experimental concepts for biological and cognitive enhancement of soldiers and civilians. American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.

#### TRIPs waiver undermines the innovation ecosystem

**Pitts 5/21** [Peter J. Pitts, a former associate commissioner of the FDA, is president of the Center for Medicine in the Public Interest. Robert Popovian is the chief science policy officer of the Global Healthy Living Foundation and a senior health policy fellow at the Progressive Policy Institute. Wayne Winegarden, Ph.D., directs the Center for Medical Economics and Innovation at the Pacific Research Institute. 5-5-2021, PRI Center for Medical Economics And Innovation “Waiving Covid-19 Vaccine Patents Is a Bad Idea and Sets a Dangerous Precedent”, 5-21-2021, <https://medecon.org/waiving-covid-19-vaccine-patents-is-a-bad-idea-and-sets-a-dangerous-precedent/> ]//AAli

Nor is such a process going to produce faster results. Historically, under compulsory rather than voluntary licensing arrangements, it has taken even legitimate generic manufacturers years to receive the formulas, work out logistical challenges, and scale up production. In one case of compulsory licensing, it took over four years to bring a generic AIDS drug to Rwanda. The World Health Organization regularly publishes a list of “essential” medications, the vast majority of which patent protections have long expired. Any generic manufacturer can therefore set itself up producing them. Yet the WHO reports that availability of these medicines in many parts of the developing world remains spotty, at best. The quality of many of these essential medicines is also questionable. Yet none of the drugs on the WHO list are in the same universe of complexity as the Covid-19 vaccines. The patent system is not the problem here. But, some ask, why should private companies enjoy the property rights to innovation driven by government funding? This question likewise misses the mark. In a study of 478 drugs less than 10 percent had a public-sector patent associated with it. While providing no gain, compulsory licensing promises lots of pain. Shunting aside patent and intellectual property rights sends a dangerous signal to innovative biopharmaceutical companies and their investors. Biopharmaceutical research is risky. It costs almost $3 billion, on average, to bring a single medicine to pharmacy shelves. Biotech investors take these risks because of strong patent protection like those in the United States. Scientists in America now develop over half of all new drugs worldwide. It’s important to understand the current advocacy for a “temporary” IP waiver. A small but vocal and influential public health policy cohort believes that IP protections are the most significant cause of global healthcare disparities. Their philosophies repeat and reinforce many misconceptions about the problem of improving global access to medicines. The reality is that, in order to save the world, we must all work together as partners. A free-market healthcare paradigm for drug development, although far from perfect, works. A well-appointed armamentarium of Covid-19 diagnostic tools, therapeutics, and vaccines – all invented in under one year, speaks to the power of today’s innovation ecosystem. That ecosystem is built on IP protections. Right now, under voluntary licensing, global production capacity for Covid vaccines and treatments is expanding and accelerating. A move to nullify IP will not result in a single resident of the developing world getting vaccinated one minute sooner.

#### The plan recapitulates IP to China, destroying competitive advantages

WSJ 5/6 [Wall Street Journal Editorial Board, WSJ Opinion Philosophy: “We speak for free markets and free people, the principles, if you will, marked in the watershed year of 1776 by Thomas Jefferson's Declaration of Independence and Adam Smith's “Wealth of Nations.” So over the past century and into the next, the Journal stands for free trade and sound money; against confiscatory taxation and the ukases of kings and other collectivists; and for individual autonomy against dictators, bullies and even the tempers of momentary majorities.” Edited by Paul A. Gigot and Daniel Henninger, “Biden’s Vaccine IP Debacle: His patent heist is a blow to the Covid fight and U.S. biotech.” The WSJ Opinion: Review and Outlook, May 6, 2021] RM

We’ve already criticized President Biden’s bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon’s wage-and-price controls.

In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, set a destructive precedent that will reduce pharmaceutical investment, and surrendered America’s advantage in biotech, a key growth industry of the future. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away.

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India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested.

Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S.

But suspending IP isn’t necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world.

Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer’s 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year.

AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But India has restricted vaccine exports to supply its own population. IP simply isn’t restraining vaccine production.

Busting patents also won’t speed up production, since it would take months for these countries to set up new facilities. Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines.

There’s also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that’s in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back?

The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America’s crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals.

Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches.

Thanks to Mr. Biden, all this could become the property of foreign governments. Licensing agreements allow developers to share their IP while maintaining quality control. Breaking patents and forcing tech transfers will enable China and low-income countries to manufacture U.S. biotech products on their own.

China’s current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. The U.S. has spent years deploring China’s theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation.

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Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck.

Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism.

Mr. Biden ought to listen to Angela Merkel. Pfizer’s partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: “The protection of intellectual property is a source of innovation and it must remain so in the future.”

At least IP is safe in Germany. Mr. Biden has sent a signal around the world that nobody’s intellectual property is safe in America.

#### China will leapfrog the US through biotech primacy

Cumbers 20 [John Cumbers, “I am the founder and CEO of SynBioBeta, the leading community of innovators, investors, engineers, and thinkers who share a passion for using synthetic biology to build a better, more sustainable universe. I publish the weekly SynBioBeta Digest, host the SynBioBeta Podcast, and wrote “What’s Your Biostrategy?”, the first book to anticipate how synthetic biology is going to disrupt virtually every industry in the world. I also founded BetaSpace, a space settlement innovation network and community of visionaries, technologists, and investors accelerating the industries needed to sustain human life here and off-planet. I’ve been involved with multiple startups, I am an operating partner and investor at the hard tech investment fund Data Collective, and I'm a former bioengineer at NASA. I earned my PhD in Molecular Biology, Cell Biology, and Biochemistry from Brown University and am originally from the UK.”) “China’s Plan To Beat The U.S. In The Trillion-Dollar Global Bioeconomy” Forbes, 2/3/2020] RM

The report, entitled “Safeguarding the Bioeconomy,” looks at how research and innovation in the life sciences is driving rapid growth in agriculture, biomedical science, information science and computing, energy, and other sectors of the U.S. economy. This economic activity—collectively referred to as the bioeconomy—presents many opportunities to create jobs, improve the quality of life, and continue to drive the U.S. economy as a whole. The report says that while the U.S. has been a leader in advancements in the biological sciences, other countries are actively investing in and expanding their capabilities in this area—and the U.S.’s lead is beginning to slip. Four reasons everyone should care about the U.S. bioeconomy It might be easy for some to dismiss the report out of hand as a bunch of alarmist professors lobbying for more research money. But when you consider all the ways that biotechnology powers the economy and impacts our daily lives, it becomes clear that this is about something more: The economy: at $1 trillion in value, the U.S. bioeconomy represents hundreds of thousands of quality, high-paying jobs for Americans. Health & medicine: innovators in the bioeconomy are making next-generation therapies for cancer and diabetes, tackling emerging diseases like Coronavirus, and even increasing human longevity. Food & farming: biotechnology is not only making agriculture more sustainable, it’s also bringing to market new and improved crops that are more nutritious, more affordable, and more delicious. The environment: humanity’s health and well-being depend on our ability to stop and reverse climate change, and we can’t do it without biological solutions that treat carbon not as a waste product, but as the starting point for chemicals and materials that today use petroleum. Considering all this, it doesn’t seem like an overstatement when the report authors say that U.S. competitiveness in the bioeconomy is key to maintaining the economic health and security of the country. The very real risks to the U.S. bioeconomy There are many things that can go wrong, causing the U.S. to lose its current edge in the global bioeconomy. Some of these are economic risks, and others present serious national security risks. All of them are related to a failure of our government to act now. Here’s a sampling of the risks to U.S. leadership at the frontiers of tech and bio: Insufficient government R&D investment. Money for basic research and development builds the foundations of the bioeconomy. We learn, achieve new results, and create new applications. Investments that help develop enabling tools, technologies, and standards have the potential to maintain the U.S. bioeconomy competitive in a global bioeconomy. Ineffective or inefficient regulations. Regulatory uncertainty stifles creative new approaches that may have unknown paths, long delays, or that might be prohibited by later changes. Inadequate workforce. The U.S.’s K-12 education system may not prepare students to study STEM subjects at the university and postgraduate level, hindering the quality of workers. A skilled workforce gives U.S. companies the best talent to choose from, and it also encourages international firms to establish research and production facilities here. Ineffective or inefficient intellectual property protections. Uncertainty over what is patentable could discourage innovators who are considering whether and how to bring their innovations to market. Patent eligibility is also important to venture capitalists and private equity investors when considering whether to invest in biotechnology companies. Cybersecurity. As biological engineering depends more and more on massive datasets, the emerging bioeconomy now exists at the intersection of information science and biotechnological science. The bioeconomy’s growing reliance on software, networking, and computer hardware tools yields the same cyber vulnerabilities present in any other sector, including hacking, sabotage, breached privacy, or theft of intellectual property. Biosafety and biosecurity risks. The tools of today’s bioeconomy are enabling new capabilities that can generate concerns regarding traditional biothreats. These can include the accidental or intentional creation or release of dangerous or lethal pathogens. Such biothreats can harm humans, animals, plants, agriculture, the environment, and materials. Risks from climate change. Food and feed crops, biofuels crops, and crops used with bio-based fermentation products are susceptible to temperature and water stresses, as well as insects and pathogens that migrate with changing weather patterns. China: the biotech elephant in the room I’ve written previously written how the Chinese government is already making substantial investments in its bioeconomy. Here are three scary statistics, courtesy of Greg B. Scott of the ChinaBio Group: China is out-investing the U.S. China’s private investors poured $14.4 billion into its bioeconomy in 2019. That compares to the United States’ more meager investment of $10.4 billion. China is building a bigger bioeconomy workforce. China graduates about 8-10 million students each year. In the U.S., that number is closer to 400,000. Many Chinese students graduating from U.S. institutions stay here, but they are increasingly returning home to start highly innovative companies. China is investing in itself. Historically, China has invested heavily in foreign companies, tech, and debt. Now we’re seeing an uptick in China-to-China investments—the country no longer needs to look abroad to find plenty of good biotech opportunities. Chinese investments have led to centers of excellence in the regional technology hub of Shenzhen, including the Institute of Synthetic Biology at the Shenzhen Institute of Advanced Sciences (SIAT) and BGI Genomics. Shenzhen will compete for technological and economic leadership with U.S. regional biotech powerhouses such as San Francisco/Silicon Valley and Boston/Cambridge in the years to come. Many of China’s long-standing challenges—environment, food, water, waste management, and rapid innovation to retain its global manufacturing competitiveness—are areas where synthetic biology is seen as a key technology for the future. In other words, synthetic biology is not just an academic pursuit for China. Rather, its leaders are thinking proactively about how biological engineering can be used to address the country’s strategic national interests—while U.S. leadership stands idly by. What do we do? So what can U.S. policymakers do to protect the U.S. bioeconomy and ensure continued technological and economic leadership in biology for the next twenty years? Straight from the top. China has made clear its ambition to become a global tech superpower, with President Xi Jinping calling science and technology one of the main battlefronts of the economy. The U.S. administration needs to step up its game, too. President Trump recently declared January 2020 to be National Biotechnology Month, citing “boundless possibilities for economic growth, national security, healthcare, manufacturing, and agriculture.” That’s the right sentiment—now we need real action. New legislation. Late last year, the U.S. House of Representatives passed the Engineering Biology Research and Development Act of 2019, which would direct the Office of Science and Technology Policy (OSTP) to implement a national research strategy for engineering biology. The explicit goal: maintain U.S. science, technology, and economic leadership in synthetic biology. The bill now resides in the Senate and awaits committee action. Legislative leadership is now needed to give this bill the appropriations necessary to give it real teeth, and then put it squarely on the President’s desk. Investing for returns. The Human Genome Project is said to have returned $141 for every dollar invested by taxpayers. While “Big Science” yields tremendous benefits for everyone, it doesn’t happen without federal funding. In 2019, politically courageous Republicans and Democrats came together to produce a 2020 final spending bill that is kind to science, in essence ignoring President Trump’s proposed cuts and instead giving increases to each of the NIH, NSF, NASA, and DOE’s Office of Science. But the U.S. isn’t even in the top ten for R&D spending as a percentage of GDP, while China continues to close in on the U.S., meaning that the U.S. is no longer the uncontested global leader in science. Leading the global bioeconomy: Have some courage There are many things the U.S. could do to protect the American bioeconomy. But above all else, policymakers need to come together and demonstrate the kind of courage and vision needed to be a world leader. Science and technology know no partisan lines. Everybody wants healthy lives, clean water, and good jobs. Federal initiative and assistance are needed to bring these benefits to everyone living in the U.S.. Today, the American synthetic biology industry may be unprepared for the global competition it will face, lacking initiative and leadership at the highest levels of government. But this could change quickly. If a country like the U.S. makes engineering biology a national priority, anything is possible in the new bioeconomy.

#### Heg solves arms races, land grabs, rogue states, and great power war

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6

From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep.

This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance.

Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,” but it was not at all inaccurate.

American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap.

Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled.

THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors.

First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment.

## Case

### Solvency

#### Patent Waiver can’t solve trade secrets or infrastructural deficits

**Rutschman et al 5/5** [Ana Santos Rutschman and Julia Barnes-Weise, Her legal scholarship has appeared or is forthcoming in UCLA Law Review, Emory Law Journal, Arizona Law Review, Yale Law Journal Forum, University of Chicago Legal Forum, Michigan Law Review Online, Annals of Health Law and Duke Law and Technology Review, among other, 5-5-2021, "The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal," Bill of Health, <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/> ]//AAli

As the toll of COVID-19 continues to increase in many countries in the Global South, there has been a renewed push to address the problem of vaccine scarcity through a waiver of patent rights. Calls for waivers have been recurring throughout the pandemic, from formal proposals introduced in 2020 by some of the larger developing economies (India and South Africa), to op-eds in mainstream media, and editorials in scientific publications, such as Nature. This push gained momentum in early May 2021, just before the meeting of the World Trade Organization’s General Council. Waiver proposals have attracted the support of prominent names in public health. Dr. Tedros Adhanom Ghebreyesus, the Director-General of the World Health Organization, endorsed patent waivers as a tool to address the current vaccine scarcity problem in an article titled Waive Covid Vaccine Patents to Put World on “War Footing.” Others — including, most recently, Dr. Anthony Fauci — have been critical of waiver proposals. In this piece, we explain the mechanics of patent waivers and argue that waivers alone are the wrong policy tool in the context of the COVID-19 pandemic. We agree with supporters of the waivers in their ultimate goal — that of scaling up the manufacturing of COVID-19 vaccines, and then distributing them according to more equitable models than the ones adopted thus far. However, we doubt that the particular types of goods at stake here can be easily replicated and produced in substantially larger quantities simply through a waiver of intellectual property rights. Vaccines and Intellectual Property: The Informational Function of Patents Intellectual property rights, and especially patent rights, are governmental grants embedded into national legal systems across the world for utilitarian reasons: longstanding intellectual property theory and policy rests on the idea that the prospect of obtaining a patent will incentivize players in research and development (R&D) to invest in areas that might be otherwise underfunded. While a vast body of research demonstrates that this utilitarian approach is not universally applicable to all types of goods (and especially to certain types of health goods), it remains the main driver of modern patent regimes. In exchange for getting this particular type of intellectual property rights, patentees disclose critical information about the invention covered by the patent. On the one hand, a patent gives the patentee lead time on the market for a relatively lengthy period of time (formally 20 years, in practice less than that, especially for products like vaccines that must undergo review and approval by drug regulators). On the other hand, by requiring that the patent applicant share information about the invention that is subsequently published by the patent office, the patent system promotes the flow of scientific and technical information that can be used by other innovators in the field. It is well known by now that existing COVID-19 vaccines — including the ones that represent the application of a new type of vaccine technology, mRNA vaccines — are covered by multiple layers of patent rights. Proponents of a patent waiver for COVID-19 vaccine emphasize the problems created by the exclusivity created by intellectual property rights, and they are correct in their diagnosis. Having adopted a legal regime that grants patent rights to any inventions meeting the substantive criteria set forth in international and national patent laws (a threshold that many of the current patent applications on COVID-19 will, in all likelihood, clear), we now face the logical consequences of such a regime: absent some kind of intervention, vaccine patent holders have the ability to refuse licensing their technology to others, even against a backdrop of vaccine scarcity. A waiver is thus portrayed as a mechanism to overcome this exclusionary ability that traditionally inheres to a patent: in light of the tragic proportions of our shared public health problem, let us do away with the exclusionary right for a certain period of time and other companies will be able to 1) replicate existing vaccines and 2) manufacture at scale so that considerably more doses of vaccine will start flowing towards populations in the Global South. These two propositions would be accurate if the information disclosed in patents were enough to increase the supply of COVID-19 vaccines. Unfortunately, it is not. A Mismatch Problem: The Informational Limitations of Patents Patents cover both processes and products. In the case of vaccines, the former category includes methods of vaccine production, while the latter covers a myriad of vaccine components, from antigens (substances used to elicit a reaction from the immune system), to inactive ingredients, such as adjuvants (substances that help enhance the immune response, like oil-in-water emulsions) and stabilizers (substances that help maintain the potency of the vaccine, like sugars), to the vaccine delivery mechanism. In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem. First, we are still left with a significant informational problem: as many commentators have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine. From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere. Second, even if all types of legal restrictions on the use of vaccine technology were lifted — or had never existed in the first place — there is simply not enough infrastructure (manufacturing facilities and equipment) nor raw materials (the components needed to manufacture and deliver vaccines) to produce and distribute COVID-19 vaccines as predicted under current waiver proposals. We have long faced a global vaccine manufacturing problem that will not be fully resolved during the current pandemic. In the case of vaccines that need to be kept at ultra-cold temperatures, these problems intensify. One of us (Barnes-Weise) has been involved in the contractual negotiations for the development, manufacturing and transfer of technology related to COVID-19 vaccines. In addition to the informational gaps described above, COVID-19 vaccine manufacturers are most concerned about how well the recipients of the technology transfer will understand and be able to implement such knowledge in making vaccines of the necessary quality. Shortages do not merely affect materials necessary to manufacture vaccines and facilities adequate to manufacture the vaccines; they also affect the availability of personnel qualified to instruct the licensee and recipient of this information. Sending an employee of this caliber out of the original manufacturing site to a partner site risks reducing the capacity of the first site. And remote instruction, necessitated by the pandemic, has its own shortcomings. In relation to the patents on the vaccines themselves, most of the concerns that the vaccine manufacturers express are around the protection of their vaccine platforms for the purposes of making future or non-COVID-19 vaccines. Moderna shared information about its patents in summer 2020. The manufacturers, as evidenced by the number of licenses to manufacture granted to date, are eager to find partners with the capabilities to expand production. It is not to their benefit to produce an inadequate supply of a highly sought-after vaccine. However, even willingness to transfer patented vaccine technology has faced numerous practical hurdles to date: 1) infrastructural limitations; 2) scarcity of raw materials; 3) concerns about licensees having the ability to actually manufacture effective vaccines in light of the infrastructural and product scarcity, even in situations in which there might be no informational gaps. A patent waiver would not address any of the practical concerns currently at the root of tech transfer negotiations involving COVID-19 vaccine technology. Compounding these problems is the fact that, should a waiver be issued, there is no legal mechanism that can compel the transfer of certain types of know-how or trade secrets should a company be unwilling to license its intellectual property — which, again, at this point in the pandemic, is not a problem we have observed. Finally, it is important to keep in mind that a waiver would be temporary: supporters of current waiver proposals should consider what will happen once demand for vaccines begins diminishing and fewer manufacturers remain on the market. Moreover, they should consider the legal and practical uncertainty that a waiver would introduce, as it is unclear how technology transfer between companies would cease (or continue) once the waiver expires

#### Alt cause and SD: Waiving IPR does nothing; bottleneck is the real problem

Stephen **Ezell 3/9** https://itif.org/publications/2021/03/09/trips-waiver-covid-19-ip-rights-wouldnt-help-vaccine-access(Stephen Ezell is 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.) [AB]

**In the face of a COVID-19 pandemic that has caused** [**2.6 million fatalities**](https://news.google.com/covid19/map?hl=en-US&mid=%2Fm%2F02j71&gl=US&ceid=US%3Aen) **worldwide, life-sciences companies have raced to bring forward a wide range of life-saving innovations,** including novel diagnostic tests like Lumira DX’s that can detect the virus within minutes; therapeutics such as Gilead’s remdesivir; and highly effective vaccines such as those from Moderna, Pfizer, and Johnson & Johnson. In fact, over 600 novel COVID-19 treatments are [under development](https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap), including 130 vaccines in global clinical trials and 176 in pre-clinical trials. **Yet, amidst this unprecedented pace of innovation, some 90 developing nations, led by India and South Africa, have petitioned the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council calling for a** [**waiver**](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True) **to suspend all intellectual property rights (IPR) associated with COVID-19 innovations, again asserting the false narrative that IP rights inhibit access to medicines.** The waiver petition itself suggests the various fallacies underlying the request. First, the waiver (initially submitted on October 2, 2020) acknowledges that, “To date, there is no vaccine or medicine to effectively prevent or treat COVID-19.” **This admission immediately confirms that intellectual property rights are not and have never been the challenge in the COVID-19 pandemic.** Rather, the challenge initially was the very lack of intellectual property; we had to, and did, discover and invent the scientific and technical knowledge necessary to understand the operation of the virus and how to defeat it with novel vaccines and therapeutics. Much of this involved new-to-the world technologies, such as novel mRNA-based vaccines. Far from being an inhibitor of this process, the robust intellectual property regimes in place in many nations contributed to a body of biomedical knowledge and technologies that provided a crucial platform for the innovation of COVID-19 solutions. Second, the [waiver](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True) petition vaguely references “several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients.” The [first](https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots) of two cited instances pertained to Labrador Diagnostic LLC, a patent-licensing firm which—although it did file a suit against a French firm, bioMerieux SA, developing coronavirus tests, in order to ensure that its IP was not infringed—has actually committed to offering its patents royalty-free to any company developing coronavirus tests. The second instance referenced Kentucky Governor Andy Beshear’s [call](https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/) for 3M to release a patent on N95 respirators. But that was it; on those two incredibly thin reeds, with nary any serious evidence whatsoever that IP rights were inhibiting access to COVID-19 treatments—let alone the fact that no COVID-19 vaccines existed at the time—the petitioners took the radical step to call for a suspension of all IPR rights pertinent to COVID-19 technologies throughout the duration of the pandemic. And while petitioners made this call on the alleged grounds of ensuring sufficient access to needed vaccines and therapeutics, their call for the suspension of every facet of IP rights on every conceivable COVID-19 related technology—even such as for copyrights and industrial designs—betrays the reality that the petitioners’ core goal isn’t really about access, but about undermining the global intellectual property rights system. To be sure, the developed world needs to be fully committed to ensuring that the world’s citizens receive the COVID-19 vaccines and therapeutics they need. But this can be accomplished through structures such as licensing and product development partnerships, without requiring an abrogation of intellectual property rights. For instance, in February 2021, the Biden administration announced it would [contribute](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort) up to $4 billion to COVAX, a vaccine alliance seeking to distribute COVID-19 vaccines to 92 low- and middle-income countries. COVAX aims to deliver at least 2 billion vaccine doses by the end of 2021, covering at least 20 percent of the most vulnerable citizens in poor- and middle-income countries. I**nnovative life-sciences companies have entered into a number of licensing agreements to facilitate dramatically expanded manufacturing of COVID-19 vaccines and therapeutics. For instance, Gilead Sciences has licensed its therapeutic remdesivir royalty-free to** [**nine generic drug manufacturers**](https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir)**, in Egypt, India, and Pakistan. AstraZeneca reached a licensing and technology transfer agreement enabling** [**India’s Serum Institute**](https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html) **to manufacture one billion vaccine doses for low- and middle-income countries. The Serum Institute has further** [**entered into manufacturing licenses**](https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/) **with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers.** Johnson and Johnson has announced plans to allocate up to [500 million vaccine doses](https://www.jnj.com/latest-news/johnson-johnson-signs-communique-on-expanded-global-access-for-covid-19-vaccines) to lower-income countries, with delivery starting by mid-2021. Companies like Johnson & Johnson are making the vast majority of these vaccine doses available on a not-for-profit basis. **Thus, the fundamental problem isn’t high prices due to IP rights; it’s dramatically scaling up manufacturing capacity. It takes** [**60 to 110 days**](https://www.cbsnews.com/news/covid-vaccine-johnson-and-johnson-factory/) **to produce one batch of COVID-19 vaccine.** When Serum Institute CEO Adam Poonawalla [was asked](https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jabs-than-anyone) if vaccine rollout was slowed because vaccine patentholders were licensing too few manufacturers to make them, he responded, **“No. There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” Poonawalla actually cited the lack of global regulatory harmonization as a far greater cause of delays in the vaccine rollout. Even Médecins Sans Frontières’ Rose Scourze acknowledged (in a January 20, 2021 *BBC* interview) that suspending patent rights “wouldn’t produce millions of more vaccines.”** Instead of forcing the disclosure of IP, policymakers should encourage the use of voluntary licensing agreements to expand production of the needed COVID-19 vaccines and therapeutics. One reason this critically matters is to ensure consistency and safety in the production of these treatments. The mRNA-based vaccines developed by Moderna and Pfizer are [incredibly complex biologic products](https://itif.org/publications/2021/01/28/covid-19-vaccines-are-even-bigger-story-you-think) that require specialized experience, expertise, and equipment to manufacture. For example, mRNA vaccines require a complicated technique known as “bioprocess” that requires specialty bioreactors to first manufacture DNA that codes for the desired mRNA sequence, and then uses a second bioprocess to create billions of identical mRNA segments. These are then wrapped in a nanolipid wrapper using yet another very specialized fluidics and mixing process, and for which there are only three facilities in the world that can execute the step of creating the liquid capsule around the RNA. Instead of simply being forced to divulge their IP or see it be compulsorily licensed to other manufacturers, in light of the extreme complexity of manufacturing COVID-19 vaccines and therapeutics, companies should have the right to evaluate potential license partners and ensure that they can meet the production standards required to safely and reliably produce COVID-19 vaccines or treatments before entering into license arrangements with them. **Indeed, this is critical for it would be disastrous if defective vaccines or therapeutics were produced at facilities not properly equipped to produce such complex treatments. As Phil Stevens and Mark Schultz** [**have written**](https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/)**, there’s simply no evidence that invalidating IP rights would achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries such as India and Brazil.** Instead of rolling back intellectual property rights, policymakers in developed and developing nations alike should focus on mechanisms to scale up production of vaccines and make them affordably available to citizens in developing countries. But to achieve that, there is simply no compelling reason for a blanket suspension of the intellectual property rights associated with COVID-19 products and technologies. For this reason, the Biden administration should continue the previous administration’s stance of opposing the waiver at the WTO TRIPS council, where deliberations resume on March 10, and reject [calls from some in Congress](https://news.bloomberglaw.com/health-law-and-business/democratic-lawmaker-pushes-biden-to-back-vaccine-patent-waiver) to endorse the proposed TRIPS waiver.

### AT Disease

#### 1] No disease extinction – impact starts at 4%

Owen Cotton-Barratt 17, et al, PhD in Pure Mathematics, Oxford, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute, 2/3/2017, Existential Risk: Diplomacy and Governance, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### 2] Their card is from April 2020, no knowledge of what covid was actually like, so the warrants of the card fail on a truth level

### AT – WTO

#### 1] X apply the Wragg evidence from the consult. WTO appellate body can literally do nothing right now. Waiver does nothing

#### 2]Countries don’t obey the WTO – they’ve hamstringed the dispute settlement process via blocking new appointments or they make their own agencies

**Armstrong 19.** Shiro Armstrong is an economist and Fellow at the Crawford School of Public Policy. He is Director of the Australia-Japan Research Centre, Editor of the East Asia Forum, Director of the East Asian Bureau of Economic Research and Research Associate at the Center on Japanese Economy and Business at the Columbia Business School.,8-8-2019, "Are Trump's tariffs legal under the WTO? It seems not, and they are overturning 70 years of global leadership," Conversation, <https://theconversation.com/are-trumps-tariffs-legal-under-the-wto-it-seems-not-and-they-are-overturning-70-years-of-global-leadership-121425> ]//AAli

President Trump’s “America First” agenda is rapidly trashing the global economic system and the rules and norms the US has championed throughout in the post war era. Mr Trump has been singling out particular countries, including China and Mexico, for punitive tariffs way in excess of those imposed on imports from other countries, a practice that may have some legality in the US but is almost certainly outlawed by the World Trade Organisation. The latest, announced on Twitter and due start to September 1, is a tariff of 10% on almost all of the $US300 billion worth of Chinese imports not subject to an earlier punitive tariff of 25%. Among them are clothes, shoes, blankets and bedding, curtains, lighting fixtures, furnishings, toys and electronic goods including mobile phones, laptops, tablets, and televisions, but only those from China. Until now, the average US tariff rate has been 2%. The new tariffs push the average rate on Chinese imports to more than 20%, close to the infamous Smoot-Hawley tariff levels that stifled global economic growth in the 1930s. China has already responded with tariffs of its own, and by slowing purchases of US agricultural products. Are Trump’s actions legal? The World Trade Organisation to which most of the world belongs and to which the US has belonged since its inception and China since 2001, has as its most important principle that “countries cannot normally discriminate between their trading partners”. It means that if tariffs are low, as they are in the United States, that low rate has to be applied to imports from all member countries, not to all but one. Exceptions are permitted only “under strict conditions”. The General Agreement on Tariffs and Trade administered by the WTO offers a tiny out relating to national security, on which Trump appears to be relying. Article XXI states that the agreement shall not prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests Subsections clarify that a member country can invoke this section (i) relating to fissionable nuclear materials; (ii) relating to the traffic in arms, ammunitions, and implements of war; and (iii) in times of war or other emergency in international relations. It’s not obvious that that there is any such emergency. Trump is threatening tariffs on automobiles and auto parts from Japan, Germany and elsewhere in the name of national security and it’s difficult to see any justification there, as well. In April this year the WTO dispute settlement panel issued a landmark ruling in a dispute between Russia and the Ukraine asserting that the panel, rather than the country imposing tariffs, had the power to determine whether or not there was an emergency. Worse still for the US (and for Russia) it found that political or economic differences between members are not sufficient, of themselves, to constitute an emergency So the US would be found to have broken the rules? Breaking the rules and being found to have broken the rules are two different things. The first step would be for another WTO member to take the United States to the dispute settlement panel and appellate body, incurring the wrath of the US and taking on the small risk of a judgement against it. The second would be for the appellate body to hear the case. Normally seven members strong, the WTO appellate body has shrunk to just three people (the minimum permissible) after the US blocked every new appointment after each four-year term expired. Two more members’ terms expire in December, and the last expires in December 2020. The body will be able to continue work on existing cases for a year or two because members whose terms have expired are allowed to continue work on cases they have started. But after December the appellate body will be unable to take on new cases. The rules themselves are under threat The era of a rules-based trade is ending. The US has gone from underwriting the rules for the past 70 years to becoming their biggest threat. The European Union and Canada are trying to get around the destruction of the body that enforces the rules by setting up their own dispute settlement system based on the existing WTO rules and will use retired appellate body judges. Other nations might join in. The United States and China — the world’s two largest economies — are engaged in a trade war that appears to be spiraling out of control, doing immense damage to the economies of each, and to worldwide GDP. A worst-case outcome is an all-out global trade war that would undoubtedly lead to global recession. That did not seem a plausible scenario two years ago, but it is now.