**Biotech DA**

***IP strikes a needed balance between innovation and access.***

[WIPO]. "Promoting access to medical innovation." 05, 2013. <https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html> Accessed on August 09, 2021. [No initials set.]    
"The rationale of the intellectual property (IP) system in general, and the patent system in particular, is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in patent applications is accessible to society. In this way, it seeks to balance competing private and public interests. Anyone applying for a patent is required to disclose the details of their technology so that the public is aware of, and can eventually use, the knowledge contained in patent documents. Patent information available through public databases, such as WIPO′s PATENTSCOPE, offers useful insights about innovation trends and freedom-to-operate, and can help shape patenting and licensing strategies. Data indicate overall long-term growth in patenting of medical technologies (a sign of renewed investment in this area) and that an increasingly diverse range of public and private users (see Figures 2 and 3), including from emerging economies, are using the international patent system. While the patent system is designed to promote innovation by providing an incentive to invest in R&D, the impact of patents on access to medical technologies is complex and much debated. Just as the existence of a patent need not be a barrier to access, the absence of a patent right does not guarantee effective access. As noted in the WHO′s Framework for Access to Medicines, access to medicines is rarely dependent on a single factor; it also includes rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems, among others. Striking an appropriate balance between encouraging medical innovation and enabling access to it has been a major preoccupation of policymakers, health activists and the private sector, since the 1990s when concerns about access came to the fore in relation to the treatment of HIV/AIDS in many African countries. The WTO′s Doha Declaration on the TRIPs Agreement and Public Health of 2001, clarified a number of rules specific to IP and helped reassure the global community that IP should not prevent access to the medicines needed in developing countries. Medical technologies are usually very expensive to develop but relatively cheap to reproduce. Without the protection conferred by a patent it would not be financially viable for companies to continue investing in research, product development and regulatory approval. If competitors could “free ride” on the cost of developing a product and were able to immediately introduce their own versions, the inventor would not get the expected financial returns thereby weakening any incentive to develop new products."

***That’s crucial, as Pharmaceutical innovation and research spurs gene editing, biotechnology and other spin off applications***

Bradshaw 17 – Julia Bradshaw is a Business News Editor at The Telegraph. (“How gene editing is revolutionising the pharmaceuticals industry,” The Telegraph, <http://www.telegraph.co.uk/business/2017/02/05/gene-editing-revolutionising-pharmaceuticals-industry/>, February 5, 2017)

Fourteen years ago the first human genome was sequenced. It cost somewhere in the region of $2.7bn (£2.16bn). It was a collaborative effort across the globe that started in 1990 and took 13 years to complete. Fast forward to today, and companies are offering genome sequencing at a mere $1,000 a pop, taking hours or days, not years, and the price continues to fall. This revolution in human genomic*s* has transformed the way we think about disease and our understanding of what causes it, paving the way for the development of treatments that are much more targeted at both the illness and the patient*,* such as cancer sufferers with a particular genetic mutation. It has also led to the rise of gene editing, a pioneering field in biotechnology whereby scientists can chop and change DNA at specific sites in an organism or cell using special molecular scissors. It’s becoming increasingly crucial in the discovery, testing and manufacture of new drugs*.*Sequencing costs have fallen dramatically “Gene editing has been something of a revolution. It has transformed from something that is fantastically difficult to carry out into a day-to-day laboratory technology,” says Dr Mike Mitchell, an analyst at Panmure Gordon. “It is now vital in both drug discovery and diagnostics and it’s oncology and precision medicine that are driving this.” The technique has taken off over the past decade. New editing tools to create genetically defined human cell lines have come to the fore, some open-access, others privately owned. The most popular is called Crispr and is accessible to all researchers. This has spurred a wave of activity in the biotech sector, with several companies now offering a suite of complex gene editing services that big pharmaceutical companies are more than happy to pay for. “We’ve had new companies with multi-billion dollar valuations coming to the market. I’m sure we will see many more active in this space, creating their own niches and applications and IP spurring further advances*,”* says Dr Mitchell.

***Affirming is devastating, Poor IP protection wrecks the healthcare and biotech industries***

George Goodno, 7-19-2017, “Weak Patent Law Endangers Healthcare Innovation,” BiotechNow, <http://www.biotech-now.org/public-policy/patently-biotech/2017/07/weak-patent-law-endangers-healthcare-innovation>, George Goodno is the Director of Communications at the Biotechnology Innovation Organization, graduated from Oklahoma State University. ZKMSU

Strong patents are the lifeblood of America’s innovation economy including the biotechnology industry. They are critical in ensuring a steady stream of capital to biotechnology companies developing innovative medicines, alternative energy sources, and insect and drought resistant crops – capital that has now begun to flow to other countries with stronger patent protections like the European Union and China. In a recent review of global patent protections, the U.S. Chamber of Commerce reported that the United States dropped from its #1 position to #10, tying with Hungary and falling behind most EU nations, Japan, and Singapore. Read the full report here. It can take a decade or more of privately funded research and development before a biotech company can bring its product to market. Only one in ten candidate drugs that make it as far as clinical trials will actually get licensed. Despite the risks of biotech investment, the industry attracts billions of dollars in new investments each year based on the promise of its innovative and patented discoveries, which will only be translated into actual commercial products providing a return on investment after years, sometimes decades, of capital-intensive investment and research efforts. Without strong and predictable protections for validly patented innovations, investors will shy away from investing in biotech innovation, degrading the ability to provide solutions to the most pressing medical, agricultural, industrial, and environmental challenges facing our nation and the world. A short-sighted approach to patent reform will undermine the promise of these initiatives. Biotechnology is one of the fields where the U.S. remains an undisputed world leader – both in terms of conceptualizing new products and bringing them to market. Our Congress should be working to preserve and nurture the sectors where the U.S. remains head and shoulders above the rest of the world, where continued advancements hold the greatest societal and economic promise. Make no mistake: the impact of weakening patent protection would be severe, and the aftershock could be devastating.

***Biotech solves a laundry list of impacts***

ICAF, 2010 (Industrial College of the Armed Forces, National Defense University, Authors include many US military colonels and faculty of the National Defense University, “Biotechnology 2010”, Spring 2010, [http://es.ndu.edu/Portals/75/Documents/industry-study/reports/2010/icaf-is-report-biotechnology-2010.pdf)//JBS](http://es.ndu.edu/Portals/75/Documents/industry-study/reports/2010/icaf-is-report-biotechnology-2010.pdf)/JBS)

Biotechnology has the potential to solve some of the most complex problems of the 21st century. As an industry, biotechnology is unparalleled in its potential to impact global health, food and water security, energy security, and the environment. This innovation-based industry is strategically significant because it impacts both national security and the sustained growth of the domestic economy. For the United States to maintain its current competitive advantage in the industry, it must focus on policy and investments which strengthen the industry’s ability to rapidly innovate and to transform innovative ideas into products and services for the global market. The purpose of this report is to conduct a strategic level examination of the biotechnology industry – an industry vital to the nation’s security and economic welfare. The study includes over fifty activities spanning lectures by leading biotechnology experts and field visits to important government and corporate organizations. The industry study program includes travel to key domestic and international biotechnology centers such as Boston, Chicago, San Francisco, Taiwan, Singapore, Malaysia, and Japan. The study methodology uses critical thinking to analyze the structure, conduct and performance of the biotechnology industry and market sectors. This includes using the five forces of competition (new entrants, supplier power, buyer power, substitutes and the degree of rivalry) to assess the capacity and capability of U.S. biotechnology firms to deliver globally competitive products and services. Additionally, the methodology evaluates the biotechnology industry’s performance in meeting national security interest and promoting economic growth.

**Microbial Resistance DA**

***IPR harmonization undermines the ability to market counterfeit drugs.***

**Ferrill**, Spring **2007**(Elizabeth – Law Clerk to the Honorable Liam O’Grady, Magistrate Judge, U.S. District Court for the Eastern District of Virginia, Clearing the Swamp for Intellectual Property Harmonization: Understanding and Appreciating the Barriers to Full TRIPS Compliance for Industrializing and Non-Industrializing Countries, University of Baltimore Intellectual Property Law Journal, p. Lexis-Nexis)

In 1994, the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was created. n2 TRIPS requires all 150 members n3 of the World Trade Organization (WTO) to provide minimal standards of protection for intellectual property (IP). n4 **TRIPS** is part of the larger WTO framework that **promotes trade liberalization**. n5 Through a series of [\*138] agreements designed to lower trade tariffs and eliminate other barriers to trade, the WTO strives to improve standards of living of all members, expand production of and trade in goods and services, and sustain development, especially in developing countries worldwide. n6 Most economists view trade liberalization as a means to wealth maximization. n7 If each country produces what it is best at producing, then output of efficiently produced products is higher worldwide. n8 Hence, countries that are the most efficient producer of a certain good would produce that good and trade with other countries for those goods it produces more efficiently, all without the cost of trade barriers. n9 Yet, countries are reluctant to unilaterally lower their trade barriers. n10 To avoid this problem, the WTO established rules for reciprocal [\*139] lowering of trade barriers. n11 In the realm of intellectual property,**harmonization**, defined as the standardization of intellectual property laws, **is analogous to trade liberalization.**If every country were to respect and protect the intellectual property rights of all other countries, inventors and creators would have the maximum incentive to create, mutually benefiting the world. More than a decade after its ratification, there remains tension and widespread noncompliance with **TRIPS**, as many countries **continue to** not **enforce foreign IP rights**, despite the potential benefits of harmonization.**Counterfeiting**, n12 which could be**mitigated by such** **enforcement, costs the world economy about $ 600 billion annually**and includes a multitude of products, such**as pharmaceuticals**, DVDs, software, toys, spare parts for cars and aircraft, and apparel. n13 This prompts the question of why complying with TRIPS and curbing counterfeiting and pirating has been so difficult over the past decade. There are a number of possible explanations.

***That’s crucial as Low-quality and counterfeit pharmaceuticals make anti microbial resistance spread globally***

**Kelesidis ’15 (**Theodoros Kelesidis – MD @ the University of Athens Medical School, Fellowship @ the UCLA School of Medicine, Specializes in Infectious Diseases. Mathew E. Falagas – MD @ the University of Athens Medical School, MSc in Epidemiology @ Harvard, Adjunct Assistant Professor of Medicine at Tufts University School of Medicine, Boston, Massachusetts, President, Board of Directors, Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece, and Director, Infectious Diseases Clinic of Henry Dunant Hospital. “Substandard/Counterfeit Antimicrobial Drugs,” 18 March 2015, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4402958/>)

Consequences for the Community **Counterfeit** and/or substandard antimicrobial **medicines** may **promote antimicrobial resistance**. **Emergence of antimicrobial resistance as a result of low-quality antimicrobials has been reported** with antimicrobials that are often used in combination therapy, such as antimalarials (45, 45, 123, 217,–220) and antituberculosis agents (1, 121, 221). The use of substandard products **may lead to underdosing of antibiotics**, **which can increase antimicrobial resistance** (2, 4, 8, 24, 222, 223). **As a result**, in some developing countries **multidrug-resistant bacteria may emerge**, and the development of travel may further promote **the spread of drug-resistant bacteria worldwide** (15, 17, 51). Furthermore, therapeutic failure **prolongs the period of contagiousness and increases the prevalence of infections** from multidrug-resistant pathogens in the community. With regard to malaria, WHO has recommended that if 10% of patients fail treatment, the malaria treatment guidelines should change (224). However, the contribution of substandard/counterfeit medicines to treatment failure for malaria needs to taken into account and addressed in future research studies. Low-quality antimicrobials **may significantly decrease confidence** in the efficacy of certain antibiotics. **Poor-quality antimicrobials may lead physicians to lose confidence** in specific antibiotics and thus to use broad-spectrum antibiotics as the drugs of choice for infections (215, 225). According to the WHO, this may lead to loss of efficacy of relatively inexpensive drugs and will promote the use of more expensive antibiotics that patients in developing countries are not able to afford. The **public confidence in health care systems and in governments may decline significantly**. If **patients** with infectious diseases do not take antimicrobials due to lack of trust in their efficacy, **they remain infectious and pose risks for global public health.**

***Disease pandemics threaten extinction.***

**Dhillon 17** [Ranu, works on building health systems in developing countries and served as an advisor to the president of Guinea during the Ebola epidemic instructor at Harvard Medical School, Harvard Business Review, 3-15-17, “The World Is Completely Unprepared for a Global Pandemic”, <https://hbr.org/2017/03/the-world-is-completely-unprepared-for-a-global-pandemic>]

We fear it is **only a matter of time before** we face a **deadlier and more contagious pathogen**, yet the threat of a deadly pandemic remains dangerously overlooked. **Pandemics now occur with greater frequency, due to** factors such as **climate change, urbanization, and international travel**. Other factors, such as a weak World Health Organization and potentially massive cuts to funding for U.S. scientific research and foreign aid, including funding for the United Nations, stand to deepen our vulnerability. **We also face the specter of novel and mutated pathogens that could spread and kill faster than diseases we have seen before.** With the advent of genome-editing technologies, bioterrorists could artificially engineer **new plagues**, a threat that Ashton Carter, the former U.S. secretary of defense, thinks could **rival nuclear weapons in deadliness**. The two of us have advised the president of Guinea on stopping Ebola. In addition, we have worked on ways to contain the spread of Zika and have informally advised U.S. and international organizations on the matter. Our experiences tell us that the world is unprepared for these threats. We urgently need to change this trajectory. We can start by learning four lessons from the gaps exposed by the Ebola and Zika pandemics. Faster Vaccine Development The most effective way to stop pandemics is with vaccines. However, with Ebola there was no vaccine, and only now, years later, has one proven effective. This has been the case with Zika, too. Though there has been rapid progress in developing and getting a vaccine to market, it is not fast enough, and Zika has already spread worldwide. Many other diseases do not have vaccines, and developing them takes too long when a pandemic is already under way. We need faster pipelines, such as the one that the Coalition for Epidemic Preparedness Innovations is trying to create, to preemptively develop vaccines for diseases predicted to cause outbreaks in the near future. Point-of-Care Diagnostics Even with such efforts, vaccines will not be ready for many diseases and would not even be an option for novel or artificially engineered pathogens. With no vaccine for Ebola, our next best strategy was to identify who was infected as quickly as possible and isolate them before they infected others. Because Ebola’s symptoms were identical to common illnesses like malaria, diagnosis required laboratory testing that could not be easily scaled. As a result, many patients were only tested after several days of being contagious and infecting others. Some were never tested at all, and about 40% of patients in Ebola treatment centers did not actually have Ebola. Many dangerous pathogens similarly require laboratory testing that is difficult to scale. Florida, for example, has not been able to expand testing for Zika, so pregnant women wait weeks to know if their babies might be affected. What’s needed are point-of-care diagnostics that, like pregnancy tests, can be used by frontline responders or patients themselves to detect infection right away, where they live. These tests already exist for many diseases, and the technology behind them is well-established. However, the process for their validation is slow and messy. Point-of-care diagnostics for Ebola, for example, were available but never used because of such bottlenecks. Greater Global Coordination **We need stronger global coordination**. The responsibility for controlling pandemics is fragmented, spread across too many players with no unifying authority. In Guinea we forged a response out of an amalgam of over 30 organizations, each of which had its own priorities. In Ebola’s aftermath, there have been calls for a mechanism for responding to pandemics similar to the advance planning and training that NATO has in place for its numerous members to respond to military threats in a quick, coordinated fashion. This is the right thinking, but we are far from seeing it happen. The errors that allowed Ebola to become a crisis replayed with Zika, and the WHO, which should anchor global action, continues to suffer from a lack of credibility. Stronger Local Health Systems International actors are essential but cannot parachute into countries and navigate local dynamics quickly enough to contain outbreaks. In Guinea it took months to establish the ground game needed to stop the pandemic, with Ebola continuing to spread in the meantime. We need to help developing countries establish health systems that can provide routine care and, when needed, coordinate with international responders to contain new outbreaks. Local health systems could be established for about half of the $3.6 billion ultimately spent on creating an Ebola response from scratch. Access to routine care is also essential for knowing when an outbreak is taking root and establishing trust. For months, Ebola spread before anyone knew it was happening, and then lingered because communities who had never had basic health care doubted the intentions of foreigners flooding into their villages. The turning point in the pandemic came when they began to trust what they were hearing about Ebola and understood what they needed to do to halt its spread: identify those exposed and safely bury the dead. With Ebola and Zika, we lacked these four things — vaccines, diagnostics, global coordination, and local health systems — which are still urgently needed. However, prevailing political headwinds in the United States, which has played a key role in combatting pandemics around the world, threaten to make things worse. The Trump administration is seeking drastic budget cuts in funding for foreign aid and scientific research. The U.S. State Department and U.S. Agency for International Development may lose over one-third of their budgets, including half of the funding the U.S. usually provides to the UN. The National Institutes of Health, which has been on the vanguard of vaccines and diagnostics research, may also face cuts. The Centers for Disease Control and Prevention, which has been at the forefront of responding to outbreaks, remains without a director, and, if the Affordable Care Act is repealed, would lose $891 million, 12% of its overall budget, provided to it for immunization programs, monitoring and responding to outbreaks, and other public health initiatives. Investing in our ability to prevent and contain pandemics through revitalized national and international institutions should be our shared goal. However, if U.S. agencies become less able to respond to pandemics, leading institutions from other nations, such as Institut Pasteur and the National Institute of Health and Medical Research in France, the Wellcome Trust and London School of Hygiene and Tropical Medicine in the UK, and nongovernmental organizations (NGOs have done instrumental research and response work in previous pandemics), would need to step in to fill the void. There is no border wall against disease. **Pandemics are an existential threat on par with climate change and nuclear conflict**. We are at a **critical crossroads**, where we must either take the steps needed to prepare for this threat or become even more vulnerable. **It is only a matter of time before we are hit by a deadlier, more contagious pandemic.** Will we be ready?

**interpretation: affirmative debaters may not specify a medicine.**

**violation: they do**

**T**

**Standards**

**1 – limits – there are infinite medicines to specify. HIV/Aids medication, Specifying justifies infinite affs and kills the neg’s ability to engage – we can’t be expected to prep for each of these affs – kills fairness bc big schools will always have access to more prep and kills education bc we wont be able to have substantive discussions on the aff.**

***2 – clash – predictable debate is key to clash – anything else leads to two ships passing in the night bc the neg doesn’t have substantive, well-researched objections to the aff. Aff is not predictable because there are infinite possibilities for the affirmative to run. kills education bc we never learn anything about both sides of the topic – aff is more likely to win bc they’re ahead on the research about their specific plan.***

**Voters –**

**1 -- Fairness – you need fairness to evaluate debate rounds – the judge needs to vote for the better debater not the better cheater. Unfair advantages in debate rounds make decisions illegitimate and hurt our ability to access real world skills. If they try to go for “fairness bad” then just vote neg because it means you’re under no obligation to evaluate their arguments fairly.**

**2 – education – it’s a voter because it’s the reason schools fund debate and the only portable skills we gain from debate are a result of education**

**Paradigm issues –**

**1 – No RVIs**

**a] logic – you don’t get to win just for proving you’re topical**

**b] chilling effect – rvis disincentivize debaters from checking abuse**

**c] theory baiting – rvis incentivize affs to be as unnegatable as possible so they can bait t or theory and win**

**2 – competing interpretations over reasonability**

**a] arbitrariness – reasonability is arbitrary and invites judge intervention**

**b] brightlines mean competing interps – it becomes a debate of whose brightline is best which is the same thing as competing interps – you’re debating about whose model is best**

**3 – drop the debater**

**a] logic – drop the argument doesn’t make sense – the shell indics their entire advocacy**

**b] severance – if they go for drop the argument it’s severance and an independent reason to negate – kicking out of the aff no-links all neg offense and forces us to restart and finish the debate in the 2nr – means there’s no way the neg can access the ballot because 2ar gets recontextualizations**

**c] norm setting – negate on t to set a norm for being fair and topical – affirming incentivizes sketchy non-t affs and better t prepouts and less substantive debate – leads to worse and less educational debates**

**Case**

***1--- Limited manufacturing and poor distribution infrastructure outweigh---their evidence.***

**Khullar 21**. [(Dhruv Khullar is a contributing writer at The New Yorker, where he writes primarily about medicine, health care, and politics. He is also a practicing physician and an assistant professor at Weill Cornell Medical College) “India’s Crisis Marks a New Phase in the Pandemic,” The New Yorker, May 13, 2021.<https://www.newyorker.com/science/medical-dispatch/indias-crisis-marks-a-new-phase-in-the-pandemic>] TDI

Jha told me that he **worries less about I.P.** and incentives than about the **practical obstacles to vaccine production.**The primary barriers to vaccine availability, he said, are not rigid intellectual-property protections but **limited manufacturing capacity and poor distribution infrastructure.** Only a **small number of companies** have the expertise needed to manufacture covid-19 vaccines, especially ones that use new mRNA technology, and **scaling up takes time.**“The world wasn’t ready to produce five or ten billion doses of covid vaccines,” Jha said. “We don’t just have all this excess capacity sitting around. You need raw materials, production capabilities, liner bags, a whole bunch of complex machinery and supplies.” Absent “a broader package of funding, supplies, manufacturing, and people with technical know-how,” Jha said, **waiving I.P. rights wouldn’t help India escape the crisis that it faces today.**

***COVID-19 vaccine patent reduction is insufficient to narrow the structural supply gap between wealthy nations and their developing counterparts – cumbersome licensing measures and lack of technological transfer ensure failure.***

***2---reducing intellectual property for covid requires the disclosure of trade secrets in order to enable effective transfer of technology to be effective – this decks solvency and increases likelihood of US circumvention.***

**Noonan ’21** -- Kevin E. Noonan is a partner with McDonnell Boehnen Hulbert & Berghoff LLP and serves as Chair of the firm’s Biotechnology & Pharmaceuticals Practice Group. (Kevin E. Noonan, "If the Devil of the WTO IP Waiver Is in the Details, What Are the Details?," Patent Docs,<https://www.patentdocs.org/2021/05/if-the-devil-of-the-wto-ip-waiver-is-in-the-details-what-are-the-details.html>, accessed 9-3-2021) //nikki

While the details of the WTO patent waiver have not been determined (or more properly negotiated), it is important to consider the structure of the international trade regime in which the waiver will operate and the consequences of any agreement defining exactly what will be waived. The GATT/TRIPS agreement is a treaty, which (of course) is an agreement between countries, and disputes and accommodations are between their governments. The extent to which a private company's patent or other IP rights are protected under the terms of these agreements depends on actions of these governments in enforcing them on the company's behalf. Thus, for protections like patents, a government can agree to "turn a blind eye" to infringement by companies in other countries (or other governments) by refusing to press the rightsholder's case before the WTO, to pressure the governments unilaterally (as in the Watch List and Special Watch List of the U.S. Trade Representative's Special 301 Report), or otherwise support a private company's private actions using an infringing country's legal system. Such "passive" actions (i.e., refusing to enforce rights in violating or "scofflaw" countries) requires very little affirmative action by a government. These are the types of de facto waivers that can be effective, for example, for patented drugs that can be produced by conventional drug production technology wherein description of an active pharmaceutical ingredient molecule. The details of COVID vaccine production have been set out in various news sources (see Neuberg et al., "Exploring the Supply Chain of the Pfizer/BioNTech and Moderna COVID-19 Vaccines"; Weiss et al., "A COVID-19 Vaccine Life Cycle: From DNA to Doses," USA Today, Feb. 7, 2021; King, "Why Manufacturing Covid Vaccine to at Scale Is Hard," Chemistry World, Mar. 23, 2021; Cott et al., "How Pfizer Makes Its Covid-19 Vaccine," New York Times, April 28, 2021). But these are certainly not disclosed in the detail necessary for commercial production, and the complexities of production are illustrated in graphics from the Times article, wherein the DNA is prepared in Chesterfield, MO and shipped to Andover, MA for mRNA production; then the mRNA shipped back to Chesterfield or Kalamazoo, MI for packaging into the vaccine nanoparticles; and then sent back to Andover for testing before release. While some of this complexity may be company-specific, it also represents the different technological requirements for preparing an effective vaccine. It is unlikely that most of the countries in favor of the waiver (except India and South Africa) have the technological infrastructure for producing the vaccine. And the company in India, the Serum Institute ("the largest vaccine maker in the world"), having the greatest likelihood of being able to reproduce the vaccine if the waiver is put in place recently was forced to "hand over its vaccines to the [Indian] government," according to an article in the New York Times (Schmall et al., "India and Its Vaccine Maker Stumble over Their Pandemic Promises," May 9, 2021). It is evident that, in the almost total absence of patents involved in COVID vaccine preparation, the disclosure needed to reproduce these vaccines (no matter how difficult that may be in practice) are protected by trade secrets. If the WTO imposes this waiver, the question will be whether the U.S. will compel disclosure of trade secret owned by U.S. companies, or have disclosed them to the extent such secrets are part of regulatory filings. Either action would constitute a "taking" under the Fifth Amendment ("Nor shall private property be taken for public use, without just compensation"); see Epstein et al., "The Fifth Amendment Takings Clause," Interactive Constitution: Common Interpretation. Seemingly simple and straightforward, almost every word in the clause is open to interpretation, none perhaps as much as determining what "just compensation" entails. It is likely that, should the government act peremptorily with regard to takings of trade secrets justified by any WTO waiver clause, the effect on trade secrets will carry the greatest consequences and be the cause of most controversy. Indeed, the prospects arising therefrom are likely some of the biggest impediments towards effectuating any waiver in a manner that could have any chance of achieving the stated goal of facilitating COVID vaccine production. This prospect also raises the issue of how any such waiver will be implemented in the U.S. Treaties are not necessarily "self-executing" and need to become enforceable through an Act of Congress. The distinguishing feature of such treaties are that "provisions in international agreements that would require the United States to exercise authority that the Constitution assigns to Congress exclusively must be deemed non-self-executing, and implementing legislation is required to give such provisions domestic legal effect." See Mulligan, "International Law and Agreements: Their Effect upon U.S. Law," Congressional Research Service 7-5700, Sep. 19, 2018. The necessity for Congress to act, although not having the heavy weight that entails approving treaties (i.e., a two-thirds majority vote in the Senate) nonetheless could be expected to face significant opposition should it be interpreted to permit the government to exercise a form of "eminent domain" over pharmaceutical companies' trade secrets. In this regard such an act could readily be characterized as "forced technology transfer" and even IP theft, should, for example, such trade secrets be capable of use to weaponize rather than immunize against viral infections. The administration's public position raises the likelihood of an infringement on private property unprecedented in the U.S. It also has implications for other aspects of foreign policy; for example, at least some of the trade secrets belong to BioNTech, a German company. Germany has not agreed to the waiver, and should the U.S disclose BioNTech's trade secrets, no doubt Germany would have cause to seek redress against America. This is but one of the possible legal consequences that the recent capitulation to the purported global "kumbaya" of the WTO waiver is likely to create. More complications will likely arise as the negotiations proceed. Provided the Administration is properly advised and the waiver properly limited (e.g., to patents) these and other deleterious consequences may be avoided. In view of the possibility of serious liability arising by improvident acquiescence to generally uninformed calls for a broad waiver, it might not be a bad idea for all those involved in innovation (universities, technology transfer offices, pharmaceutical companies, patent lawyers, and economists) counter these opinions with the facts and make their viewpoints known and voices heard.

***3---- SQUO Solves: COVAX delivered vaccines to more than 100 economies 42 days after first international delivery***

**WTO 21.**[World Trade Organization, “COVAX reaches over 100 economies, 42 days after first international delivery.” WTO. April 8 2021.<https://www.unicefusa.org/stories/covax-mission-forges-ahead-vaccinate-world-against-covid-19/38636>. ] /Triumph Debate

**The COVAX Facility has now delivered life-saving vaccines to over 100 economies since making its first international delivery to Ghana**on 24 February 2021. So far, more than 38 million doses of vaccines from manufacturers AstraZeneca, Pfizer-BioNTech and Serum Institute of India (SII) have now been delivered, including 61 economies eligible for vaccines through the Gavi COVAX Advance Market Commitment. COVAX aims to supply vaccines to all participating economies that have requested vaccines, in the first half of 2021, despite some delays in planned deliveries for March and April. More than one hundred economies have received life-saving COVID-19 vaccines from COVAX, the global mechanism for equitable access to COVID-19 vaccines. The milestone comes 42 days after the first COVAX doses were shipped and delivered internationally, to Ghana on 24 February 2021. **COVAX has now delivered more than 38 million doses across six continents, supplied by three manufacturers, AstraZeneca, Pfizer-BioNTech and the Serum Institute of India (SII). Of the over 100 economies reached, 61 are among the 92 lower-income economies receiving vaccines funded through the Gavi COVAX Advance Market Commitment (AMC).**Despite reduced supply availability in March and April – the result of vaccine manufacturers scaling and optimizing their production processes in the early phase of the rollout, as well as increased demand for COVID-19 vaccines in India – COVAX expects to deliver doses to all participating economies that have requested vaccines in the first half of the year. “In under four months since the very first mass vaccination outside a clinical setting anywhere in the world, it is tremendously gratifying that the roll-out of COVAX doses has already reached one hundred countries,” said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance. “COVAX may be on track to deliver to all participating economies in the first half of the year yet we still face a daunting challenge as we seek to end the acute stage of the pandemic: we will only be safe when everybody is safe and our efforts to rapidly accelerate the volume of doses depend on the continued support of governments and vaccine manufacturers. As we continue with the largest and most rapid global vaccine rollout in history, this is no time for complacency.” **“COVAX has given the world the best way to ensure the fastest, most equitable rollout of safe and effective vaccines to all at-risk people in every country on the planet,” said Dr Tedros Adhanom Ghebreyesus, WHO Director-General.**“If we are going to realize this great opportunity, countries, producers and the international system must come together to prioritize vaccine supply through COVAX. Our collective future, literally, depends on it.” "This is a significant milestone in the fight against COVID-19. Faced with the rapid spread of COVID-19 variants, global access to vaccines is fundamentally important to reduce the prevalence of the disease, slow down viral mutation, and hasten the end of the pandemic,” said Dr Richard Hatchett, CEO of the Coalition for Epidemic Preparedness Innovations (CEPI). **“The extraordinary scientific achievements of the last year must now be matched by an unprecedented effort to protect the most vulnerable, so the global community must remain firmly focused on reducing the equity gap in COVID-19 vaccine distribution."** “In just a month and a half, the ambition of granting countries access to COVID vaccines is becoming a reality, thanks to the outstanding work of our partners in the COVAX Facility,” said Henrietta Fore, UNICEF Executive Director. “However, this is no time to celebrate; it is time to accelerate. With variants emerging all over the world, we need to speed up global rollout. To do this, we need governments, along with other partners, to take necessary steps to increase supply, including by simplifying barriers to intellectual property rights, eliminating direct and indirect measures that restrict exports of COVID-19 vaccines, and donating excess vaccine doses as quickly as possible.” According to its latest supply forecast, COVAX expects to deliver at least 2 billion doses of vaccines in 2021. In order to reach this goal, the COVAX Facility will continue to diversify its portfolio further, and will announce new agreements with vaccine manufacturers in due course. Furthermore, in March it was announced that the United States government will host the launch event for the 2021 Gavi COVAX AMC Invest Opportunity to catalyze further commitment and support for accelerated access to vaccines for AMC-supported economies. An additional US$ 2 billion is required in 2021 to finance and secure up to a total of 1.8 billion donor-funded doses of vaccines**. COVAX is also working to secure additional sourcing of vaccines in the form of dose-sharing from higher income countries.**

***6--- IPR is not the cause of medicine inequality. Multiple alternative causes exist***

**Haugen 2021** [Hans Morten, Professor of International Diakonia at the VID Specialized University, Oslo, Norway, The Journal of World Intellectual Property, "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?" March 18, <https://onlinelibrary.wiley.com/doi/10.1111/jwip.12187>

This article analyzes the context for the allegation that IP is among the crucial factors in promoting health innovation globally, and not preventing the universal and equitable access to vaccines, even if supply of medicines is held by developed countries to be “difficult” (WTO Secretariat, 2020a). Biotechnology actors expressed criticism of the UN High-level Panel on Access to Medicines (2016), arguing that **IP tends to be overemphasized in debates over access** to medicines, **ignoring** the wider context of **what impedes such access** (International Council of Biotech Associations [ICBA], 2016; Biotechnology Innovation Organization [BIO], 2016). Hence, **developed countries** and biotech associations **concur in identifying weak funding** of health care **and lack of manufacturing capacity as constituting the** core of the **problem of access** (WTO Secretariat, 2020a; see also U.S. Department of State, 2016), **as well as regulatory inefficiencies, trade policies and inadequate** health **insurance** (ICBA, 2016).

***7----[Reisner et al] There’s no nuclear winter. Prefer our study – it has 9 PhD’s with experts in every relevant scientific field.***

**Reisner et al 2018[**[Jon Reisner](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Reisner%2C+Jon) - Climate and Atmospheric Sciences PhD at Los Alamos National Laboratory;[Gennaro D'Angelo](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=D%27Angelo%2C+Gennaro) – PhD[Los Alamos National Laboratory](https://www.researchgate.net/institution/Los_Alamos_National_Laboratory),[Theoretical Division](https://www.researchgate.net/institution/Los_Alamos_National_Laboratory/department/Theoretical_Division2)[Eunmo Koo](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Koo%2C+Eunmo) - Ph.D., Mechanical Engineering, University of California at Berkeley, Expertise: Atmospheric fluid dynamics, Modeling fluid-solid interactions, Fire spread in urban and wildland environment, Wind energy harvest, High-performance computing simulations;[Wesley Even](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Even%2C+Wesley) - Ph.D. Physics - Louisiana State University, Expertise: Computational Physics, Astrophysics[Matthew Hecht](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Hecht%2C+Matthew) – Expert in Climate and Ocean Modeling[Elizabeth Hunke](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Hunke%2C+Elizabeth) - Ph.D., Program in Applied Mathematics, University of Arizona, Expertise: Sea Ice Models;[Darin Comeau](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Comeau%2C+Darin) – PhD, Applied Mathematics, University of Arizona , Expert in High dimensional data analysis, statistical and predictive modeling, and uncertainty quantification, with particular applications to climate science, as well as process-based modeling of the cryosphere;[Randall Bos](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Bos%2C+Randall) – PhD, Expert in Nuclear Weapon Effects Modeling and Simulation[James Cooley](https://agupubs.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Cooley%2C+James) - Ph.D. -- Physics, University of Maryland, Expert in Weapon Physics, Emergency Response, Computational Physics, Verification, and Validation (2018). Climate impact of a regional nuclear weapons exchange: An improved assessment based on detailed source calculations. Journal of Geophysical Research: Atmospheres , 123 , 2752 – 2772. <https://doi.org/10.1002/2017JD027331> Received 20 JUN 2017 Accepted 1 FEB 2018 Accepted article online 13 FEB 2018 Published online 14 MAR 2018 ©2018. The Authors. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distri- bution in any medium, provided the original work is properly cited, the use is non-commercial and no modi fi cations or adaptations are made.] LHSBC

Abstract We present a multiscale study examining the impact of a regional exchange of nuclear weapons on global climate. Our models investigate **multiple phases of the effects of nuclear weapons** usage, including growth and rise of the nuclear fireball, ignition and spread of the induced fi restorm, and **comprehensive Earth system modeling** of the oceans, land, ice, and atmosphere. This study follows from the scenario originally envisioned by Robock, Oman, Stenchikov, et al. (2007, <https://doi.org/10.5194/acp-7-2003-2007>), based on the analysis of Toon et al. (2007, <https://doi.org/10.5194/acp-7-1973-2007>), which assumes a regional exchange between India and Pakistan of fi fty 15 kt weapons detonated by each side. We expand this scenario by modeling the processes that lead to production of black carbon, in order to re fi ne the black carbon forcing estimates of these previous studies. When the Earth system model is initiated with 5 × 10 9 kg of black carbon in the upper troposphere (approximately from 9 to 13 km), the impact on climate variables such as global temperature and precipitation in our simulations is similar to that predicted by previously published work. However, while our thorough simulations of the fi restorm produce about 3.7 × 10 9 kg of black carbon, we fi nd that the vast majority of the black carbon **never reaches an altitude above weather systems** (approximately 12 km). Therefore, our Earth system model simulations conducted with model-informed atmospheric distributions of black carbon produce signi fi cantly lower global climatic impacts than assessed in prior studies, as the carbon at lower altitudes is more **quickly removed from the atmosphere**. In addition, our model ensembles indicate that statistically signi fi cant effects on global surface temperatures are limited to the fi rst 5 years and are much smaller in magnitude than those shown in earlier works. None of the simulations produced a nuclear winter effect. We fi nd that the effects on global surface temperatures are not uniform and are concentrated primarily around the highest arctic latitudes, dramatically **reducing the global impact on human health and agriculture** compared with that reported by earlier studies. Our analysis demonstrates that the probability of significant global cooling from a limited exchange scenario as envisioned in previous studies is **highly unlikely**, a **conclusion supported by examination of natural analogs,** such as large forest fires and volcanic eruptions.