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#### Apocalyptic pandemic reps lock in a neoliberal risk society of anxiety and health inequality that spreads disease. Independently, the aff masks health neoliberalism by spreading vaccine arms races horizontally instead of vertically.

Mannathukkaren 14

(Nissim Mannathukkaren, Dept. Chair and Associate Prof. of International Development Studies @ Dalhousie University, “Pandemics in the age of panic,” November 22, 2014, <http://www.thehindu.com/features/magazine/social-media-should-be-a-positive-force-and-public-health-systems-should-focus-on-prevention-of-epidemics/article6624674.ece>)

\*Evidence is edited to correct gendered language\*

If natural disasters induce panic, so do pandemics. In recent years, we have seen a series of pandemics: AIDS, avian influenza, SARS and H1N1. Now, we are in the midst of an epidemic, Ebola, which — according to experts — can acquire pandemic proportions. Natural disasters and pandemics have existed in the pre-modern era as well but what is remarkable is that, in the modern era, the attitudes towards hazards — both natural and man-made — have drastically changed. Panic is the order of the day, especially in sanitised spaces of the developed West. Medical scholars, Luc Bonneux and Wim Van Damme, term panic itself as a pandemic.

As they point out, in 1999, Belgium slaughtered seven million chicken and 60,000 pigs when dioxin, a cancer-causing chemical, entered animal feed. Not one person died from dioxin poisoning. In 2005, the chief avian flu coordinator of the UN predicted that 150 million people could be killed by the flu. However, in 10 years, it has killed less than 400 people. The same apocalyptic predictions were made about BSE/CJD, SARS, and H1N1 as well.

Media coverage and the responses of governments and people to Ebola and recent pandemics tell us an important and paradoxical truth: we might be living in an era that is the apogee of human scientific advancements but this has not necessarily mitigated our fears and panic about potential dangers. This has led theorists to argue that we live in a ‘risk society’, a society that generates a lot of risks precisely because it is obsessed with, as the sociologist Anthony Giddens puts it, “the aspiration to control and particularly with the idea of controlling the future.” Traditional cultures did not have a notion of risk as diseases and natural disasters were taken for granted and were attributed to God or fate.

Interestingly, many of the risks in the modern era, as Giddens elaborates, are manufactured by the “very progression in human development, especially by the progression of science and technology.” Diseases caused by industrial pollution, natural disasters caused by environmental destruction, man-made disasters like Bhopal gas tragedy, Chernobyl and Fukushima nuclear accidents, and latrogenesis — adverse effects caused by medical intervention and modern medicines — are examples of these manufactured risks. In the U.S., scholars estimate that 2,25,000 deaths annually are due to latrogenic causes, and is the third leading cause of death after heart disease and cancer! Thus, science and technology itself generates new uncertainties as it banishes old ones and fear of the unknown cannot be eliminated by further scientific progress.

We have to read the coverage of, and response to, Ebola in this wider context of a risk society. Politics of fear, panic, and scaremongering are inevitable outcomes of such a society. Look at the panic around Ebola in the U.S., where so far not one citizen has died of the disease. A nurse returning after treating Ebola patients in Sierra Leone has won a court order against a mandatory quarantine order imposed by the state. Australia and Canada have imposed visa ban on citizens travelling from the affected countries, violating WHO’s International Health Regulations.

Renowned journalist Simon Jenkins argues that “we have lost control of the language of proportion” in responding to Ebola and other pandemics. Similarly, other journalists have severely criticised the media’s coverage of Ebola. The scaremongering is seen in absurd and irresponsible statements like Ebola is ‘the ISIS of biological agents!’ One major responsibility of the mainstream media, other than providing detailed and proper information about the disease itself, is to enlighten the public about the socio-economic and political conditions that govern health and healthcare systems in various societies, which in turn impact the origin and spread of pandemics. Without educating the public about the root causes that condemn the poorer parts of the world to bear the brunt of global pandemics, the media becomes a handmaiden of the powers — developed countries and pharmaceutical corporations — that control global health.

This lack of knowledge about larger forces also adds to risks and the resultant panic. Thus, in the 2009 H1N1 pandemic, the media’s role in the investigation of allegations of whether it was a false pandemic was nothing to be proud of. The head of health at the Council of Europe had raised questions about the role of pharmaceutical corporations in the declaration of H1N1 as a pandemic. Later, an investigation by the British Medical Journal found that medical experts advising WHO on H1N1 had financial ties with pharmaceutical companies producing the vaccine for the pandemic. As all the developed countries stocked up on the vaccines, reportedly, the pharmaceutical companies made profits ranging from $ 7-10 billion.

In this context, the media’s role in the coverage of pandemics raises questions. Where are the stories in the media about the lack of vaccines for Ebola, 40 years after the disease emerged? Or about the drug firms now in the race to produce a vaccine (the share prices of one of the companies ahead in the race have shot up exponentially)?

While certain prominent Western media houses have definitely pushed the panic button with regard to Ebola, the hard data about the overall coverage as studied by the Foreign Policy magazine indicates that it is not the case. But this study is merely restricted to the English language coverage. Further, the mainstream media has failed miserably in countering the serious issue of the racialisation of Ebola (as with AIDS before) as an African disease caused and spread merely by its cultural practices.

In a risk society, we have to confront new unknowns too, like social media and its impact. One media source called Ebola ‘the first major outbreak in the era of social media’. But, in the coverage of the outbreak, social media has reportedly been a negative force spreading misinformation and rumours that, in some cases, even led to deaths due to dangerous treatments administered.

#### The alternative is to adopt a social medicine approach to health.

Mohan J. DUTTA 15, Professor and Head of the Department of Communications and New Media at the National University of Singapore, Adjunct Professor of Communication at the Brian Lamb School of Communication at Purdue University [*Neoliberal Health Organizing*, 2015, p. 231-234]

Latin American social medicine depicts a distinct and long strand of theorizing of health systems that challenges the liberal capitalist organizing of health, grounded in the organizing principles of social medicine and noting [END PAGE 231] that changing the overarching structures is central to transforming the conditions of poor health (Waitzkin, 1991, 2011; Waitzkin & Modell, 1974). That health is constituted within broader social conditions is the basis for research, teaching, clinical practice, and activism in socialist medicine, with early roots in Latin America. Social medicine thus connects health, healing, and health care delivery to the politics of social change and structural transformation, clearly voicing an activist agenda directed at transforming the unequal social conditions.

One of the earliest influences of social medicine was evident in the work of the medical student activist Salvador Allende, who would later become the president of Chile. In his book The Chilean Medico-Social Reality, Allende (1939) outlined the social conditions in Chile that resulted in poor health outcomes, emphasizing the broader conditions of foreign debt dependence, underdevelopment, international dependence, and resource consolidation in the hands of the local elite. Proposing social rather than medical solutions to health, Allende emphasized “income redistribution, state regulation of food and clothing supplies, a national housing program, and industrial reforms to address occupational health problems” (Waitzkin, 2011, p. 160). In his political life, Allende sought reforms in the Chilean national health service, complemented by reforms in the housing and nutrition areas, efforts at national income redistribution, and minimizing the role of multinational corporations.

The individualized model of public health that sees health and illness as a dichotomy is interrogated by the framework of social medicine that suggests that health and illness exist in a dialectical relationship that is dynamic and is continually shifting on the basis of social conditions, structures, cultural practices, economic production, reproduction, marginalizing practices, and processes of political participation. Thus, interventions in social medicine point toward the necessity for transforming the underlying relationships of production and resource distribution, resisting the public health narrative of interventions as mechanisms for improving economic productivity. Taking a social-class-driven approach to health inequities, Latin American social medicine sees the problems with health being situated within means of economic production, patterns of ownership of means of production, and control over productive processes. Therefore, health is approached from the framework of transforming the processes of economic production and labor processes.

The dominant framework of health as integral to growth and economic productivity is questioned by the framework of social medicine that situates the relationship between health and illness amid the very processes of economic organization, distribution of economic resources, and the pervasive effects of social class on health services and health outcomes. [END PAGE 232] The innovations in organizing of health structures in Chile, Cuba, Mexico, Bolivia, and Venezuela offer invaluable insights about the possibilities of alternative organizing that seek to redo the entire structure of social organizing that constitute health. The strong health indicators in Cuba demonstrate the effectiveness of a health system that is committed to addressing the structural determinants of health, creating equitable contexts for the realization and delivery of health (Campion & Morrissey, 2013). Social medicine research has looked at the relations among work, reproduction, the environment, and health, describing in-depth the material conditions that constitute health. For instance, researchers studying health in Mexico within the context of unions and local communities have documented health problems that relate to work processes and the environment. Similarly, researchers in Chile have documented the relations between gender, work, and environmental conditions. A key strand of social medicine examines the relationship between violence and health, connecting violence to poverty, the structures of organizing, and the inequities in ownership of processes of economic production. Investigations of violence attached to the U.S.-supported dictatorship in Chile, the violence connected to narcotics traffic and paramilitary operations, and the violence within the broader structures of the state-imperial networks draw linkages to the broader political economic configurations of neoliberalism.

Emerging from the broader framework of social medicine, the Barrio Adentro movement in Venezuela, started by former president Hugo Chavez, offers insights into structures and processes of alternative organizing of health, connecting local community structures, community ownership, and community solutions with state infrastructures and state-driven public health resources and solutions (Briggs & Mantini-Briggs, 2009; Muntaner et al., 2006; Waitzkin, 2011). The state-driven referendum by the Chavez government to create public health infrastructures and structures of delivery of integrated family medicine, build preventive infrastructures, and develop community health resources in extremely marginalized communities is supported by massive mass-based participation in popular politics and widespread community participation in developing local community infrastructures, community-based resources of problem solving, and community decision-making capacities. The community health centers built within the barrios serve approximately 250 families and are staffed with one integrated family care doctor, one community health worker, and one health promoter. The community health centers are stocked with medical supplies. The health team not only provides health care but also conducts health surveys in the communities and makes home visits for patients that are too ill to travel to the health centers. The Barrio Adentro is integrated with other missiones addressing education, food insecurity, housing, and [END PAGE 233] unemployment, addressing health within a broader structural context (Muntaner et al., 2006). Local community participatory processes are connected with state-driven processes of building community health infrastructures at the local level.

The narrative of Barrio Adentro offers an alternative to the neoliberal narrative of the community in mainstream health communication and yet is marked by its absence from disciplinary discourses. Similarly, social medicine and its tradition of addressing the structural contexts of health is marked by its absence from the dominant discourses of health communication. A review of the two major collections of health communication scholarship, The Routledge Handbook of Health Communication and The Handbook of Global Health Communication, depicts the marked absence of the Latin American innovations of social medicine from the discursive space. Opportunities for resistance to neoliberal organizing of health structures and the invitation to imagine alternative possibilities is grounded in materially grounded concrete politics of popular participation in supporting state policies for building public health and health care infrastructures, complemented by local processes of participation in the creation of health solutions.

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#### CP – States should comply with the biological weapons convention

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#### CP Text: Vaccine developers should enter into binding contractual agreements with generic producers to ensure the quality of generic products and establish royalty rates on generic sales. The member nations of the WTO should publicly declare their support of legitimate compulsory licensees in the cases where voluntary requests have been ignored.

#### Solves

Silverman 3/15 [Rachel Silverman is a policy fellow at the Center for Global Development where she leads policy-oriented research on global health financing and incentive structures. Silverman’s current research focuses on the practical application of results-based financing; global health transitions; efficient global health procurement; innovation models for global health; priority-setting for UHC; alignment and impact in international funding for family planning; and strategies to strengthen evidence and accountability. BA with distinction in international relations and economics from Stanford University.) “Waiving vaccine patents won’t help inoculate poorer nations” Washington Post, PostEverything Perspective, <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/>] RM

There are better options than broadly waiving IP rules — notably, encouraging (and pressuring) vaccine manufacturers to cooperate and share knowledge with partners across the globe. Voluntary licensing is one route: It’s a common arrangement in which developers enter into binding contractual agreements with generic producers. Generic manufacturers get permission, know-how and assistance from the patent-holder to produce the vaccine for sales in specified markets; in exchange, the patent-holder can ensure quality of the generic product and may receive royalties on its sales, usually representing less than 10 percent of sales value.

These royalties may be lower than the profit margin on direct sales; for example, Pfizer expects a 25 to 30 percent profit on its vaccine sales, or roughly $5 for every $19.50 dose. (The U.S. government has agreed to buy 300 million doses at that price.) But voluntary licensing deals offer a new revenue stream that would otherwise be captured by competitors — not to mention good publicity. Already, **voluntary licensing deals from AstraZeneca and Novavax are facilitating large-scale production in India, Japan and South Korea**; many of the resulting vaccines are destined for lower-income countries through Covax.

The best route to vaccine equity involves creating the conditions to facilitate more of these voluntary deals.

How can governments and activists help push things in the right direction? By lifting the export curbs on materials such as filters and bioreactor bags intended to protect domestic supply, countries can help lubricate supply chains, creating a better environment for cross-national collaboration. Governments and development-finance institutions can invest to build up the capabilities of potential vaccine manufacturing plants, making it easier for originators to say yes. Domestically, the Biden administration did something like this when it [invested](https://www.merck.com/news/merck-to-help-produce-johnson-barda-to-provide-merck-with-funding-to-expand-mercks-manufacturing-capacity-for-covid-19-vaccines-and-medicines/) $269 million under the Defense Production Act to prepare Merck’s manufacturing facilities to produce the Johnson & Johnson vaccine — a crucial plank of the [joint production deal](https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html) announced this month. Similar efforts are underway abroad. On March 12, for example, the “Quad” — the United States, India, Japan and Australia — [announced](https://www.reuters.com/article/us-usa-asia/u-s-india-japan-and-australia-counter-china-with-billion-dose-vaccine-pact-idUSKBN2B40IP) a joint pledge to produce and disseminate 1 billion vaccine doses; as part of this effort, the Biden administration [announced](https://in.usembassy.gov/dfc-announces-support-for-manufacturing-of-vaccines-during-quad-summit/) that it would help finance an Indian generic manufacturer to make coronavirus vaccines, including the Johnson & Johnson product. The contractual language of licensing deals can explicitly protect IP from broader dissemination, helping originators feel more comfortable sharing commercially valuable information.

Sticks as well as carrots can facilitate partnerships. Under [existing World Trade Organization rules](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm), countries already have the right to issue “compulsory licenses” in certain cases pertaining to public health, allowing them to produce or import generic health products without permission from the patent-holder. Advocates correctly point out that countries face potential retaliation from industry and wealthy governments when they try to use these tools — a strong disincentive. (In 2006-2007, Thailand’s use of compulsory licenses to access more affordable AIDS drugs led the United States to revoke preferential trade status for some Thai exports.) This should change. The Biden administration and other global leaders should make clear that they will support legitimate compulsory licensees of coronavirus vaccines in cases where a valid voluntary license request has been rejected or ignored.

**But compulsory licensing is vastly inferior to voluntary deals in the case of vaccines, because with the former the generic producer would still need to figure out how to make the vaccines without the originator’s assistance — again, an extraordinarily difficult task.** It is useful mainly as a threat held in reserve, paired with the “carrots” of subsidies to local plants and so on. **Firms may choose to play ball on voluntary licensing deals rather than face a mess of legal challenges and bad publicity.** This month, for example, Canadian biotech firm Biolyse Pharma publicly requested a voluntary license to manufacture the Johnson & Johnson vaccine for global distribution. If Johnson & Johnson is unwilling, Biolyse made clear in its announcement, the company will appeal to the Canadian government for a compulsory license. The ball is now in Johnson & Johnson’s court — but this seems like the type of offer it should choose to accept, **both for the global good and its self-interest**.

Scaling up vaccine production is an imperative for equitable global access and an end to the pandemic**. But it is smart incentives for sharing knowledge, not the wholesale elimination of intellectual-property rights, that will get us to the finish line.**

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#### 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.

#### 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.

#### Independently, biotech heg key to prevent bioterror, Chinese biostrikes, disease prevention, biodiversity, and climate change – IP theft is the core concern

Moore 20 Scott Moore, Director of the Penn Global China Program at the University of Pennsylvania, Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S. Department of State, Giorgio Ruffolo Post-Doctoral Research Fellow with the Belfer Center for Science and International Affairs at Harvard University, Truman, Fulbright, and Rhodes Scholar., The Brookings Institution - Global China - Assessing China's Growing Role in the World, "CHINA’S ROLE IN THE GLOBAL BIOTECHNOLOGY SECTOR AND IMPLICATIONS FOR U.S. POLICY", APRIL 2020, https://www.brookings.edu/wp-content/uploads/2020/04/FP\_20200427\_china\_biotechnology\_moore.pdf - BD

IMPLICATIONS

The certainty that China will play an increasingly important role in the global biotechnology sector poses several issues for U.S. policymakers. The gravest of these pertain to national security. Though there is presently no sign that China’s capabilities exceed those of the United States, some researchers have noted that biotechnology is a focus of increasing attention by the People’s Liberation Army.42 U.S. policymakers and security analysts have also raised concerns that the dominant market position of Chinese firms in producing active pharmaceutical ingredients might allow Beijing to disrupt U.S. access to lifesaving drugs in the event of a conflict.43 On the other hand, the use of tools like CRISPR, which is increasingly inexpensive and easy to use, by terrorists and non-state actors to potentially create novel bioweapons poses severe security threats to both the United States and China. It would seem to be in the interest of all states, including China, to strengthen efforts, currently led mostly by the private sector, to prevent dangerous actors from gaining access to DNA templates and other relevant materials.44

Though these prospects are alarming, the theft and use of biomedical data presents more immediate policy concerns. American life sciences research institutions have been subject to what U.S. officials characterize as prolific intellectual property theft and non-traditional intelligence collection by Chinese actors.45 At home, Beijing has already incorporated biometric data on certain populations, such as the Uighur minority group, into its already-formidable social control and surveillance apparatus.46 Chinese actors also appear to have targeted foreign citizens for covert biomedical data collection.47 Last year, the U.S. government forced a Chinese firm to sell its majority stake in an American social network that aggregates health care data from users, primarily over worries this information could be used to persuade Americans with access to sensitive information to spy for China.48 Such added U.S. government scrutiny has contributed to a sharp decline in Chinese investment in the U.S. biotechnology sector. Though small overall, such investment had been growing rapidly, and in 2018 the biotechnology sector constituted the single largest source of Chinese investment in the U.S. overall, surpassing real estate.49

As this impact suggests, access to and control over biomedical data also has profound implications for the economic competitiveness of the U.S. biotechnology sector. Many frontier areas of biotechnology, including the use of artificial intelligence for biomedical applications, depend on access to large quantities of individual patient data. Chinese biotechnology firms are likely to have access to larger quantities of such data than their competitors elsewhere thanks to the size of China’s population and relatively weak rules governing data collection and sharing. An existing biomedical database of patients from China’s national health care system, for example, allegedly covers some 600 million patients.50

The Chinese government is moreover increasingly aggressive about preventing foreign firms and organizations from accessing such data. In 2016, biomedical data was proclaimed a “national strategic resource,”51 and the export of such data is strictly controlled. Rules specifically bar any foreign use of Chinese biomedical data that “may jeopardize national security, national interests, or public security,” and in 2018 these were used to shut down several high-profile scientific collaborations including one involving Peking University and the University of Oxford.52 It should be noted, however, that while data quantity is important, so is data quality, and a combination of poor and inconsistent record-keeping and limited population diversity may diminish the utility of biomedical data produced in China for key applications like therapeutics development.53 In any case, the availability of biomedical datasets will be a key determinant of the relative competitiveness of the U.S. and Chinese biotechnology industries going forward.

A final, and more hopeful, policy implication of China’s growing role in biotechnology is its potential to help address shared global challenges like infectious disease prevention and biodiversity protection. In the near term, the COVID-19 crisis has highlighted the need for expanded international cooperation on epidemiological data collection and analysis, vaccine development, and other areas related to biotechnology. While China’s openness to such cooperation at the moment is unclear, there are likely to be future opportunities to engage China in COVID-19 tracing, vaccine development, and deployment initiatives in third countries, especially in the less-developed world. In the longer term, synthetic biology, especially the use of gene drives to rapidly spread genetic modifications throughout a population, offers great promise to eliminate insect-borne diseases like malaria, and could also help endangered species adapt to climate change effects. As the 21st century advances, advanced biotechnology will both demand new forms of global governance and present new arenas for both competition and cooperation between researchers, business leaders, and policymakers.54

#### China uses biotech offensively

Kania and Vonrndick 19 [Elsa Kania is an Adjunct Senior Fellow with the Technology and National Security Program at the Center for a New American Security. She is also a Ph.D. candidate in Harvard University’s Department of Government. Her views are her own. Wilson VornDick consults on national security, emerging technologies, and China for Duco and Rane.) “Weaponizing Biotech: How China's Military Is Preparing for a 'New Domain of Warfare'” Defense One, Commentary, China, Biowarfare, 8/14/2019] RM

We may be on the verge of a brave new world indeed. Today’s advances in biotechnology and genetic engineering have exciting applications in medicine — yet also alarming implications, including for military affairs. China’s national strategy of military-civil fusion (军民融合) has highlighted biology as a priority, and the People’s Liberation Army could be at the forefront of expanding and exploiting this knowledge.

The PLA’s keen interest is reflected in strategic writings and research that argue that advances in biology are contributing to changing the form or character (形态) of conflict. For example:

In 2010’s War for Biological Dominance (制生权战争), Guo Jiwei (郭继卫), a professor with the Third Military Medical University, emphasizes the impact of biology on future warfare.

In 2015, then-president of the Academy of Military Medical Sciences He Fuchu (贺福初) argued that biotechnology will become the new “strategic commanding heights” of national defense, from biomaterials to "brain control" weapons. Maj. Gen. He has since become the vice president of the Academy of Military Sciences, which leads China’s military science enterprise.

Biology is among seven "new domains of warfare" discussed in a 2017 book by Zhang Shibo (张仕波), a retired general and former president of the National Defense University, who concludes: “Modern biotechnology development is gradually showing strong signs characteristic of an offensive capability,” including the possibility that “specific ethnic genetic attacks” (特定种族基因攻击) could be employed.

The 2017 edition of Science of Military Strategy (战略学), a textbook published by the PLA’s National Defense University that is considered to be relatively authoritative, debuted a section about biology as a domain of military struggle, similarly mentioning the potential for new kinds of biological warfare to include “specific ethnic genetic attacks.”

These are just a few examples of an extensive and evolving literature by Chinese military scholars and scientists who are exploring new directions in military innovation.

Following these lines of thinking, the PLA is pursuing military applications for biology and looking into promising intersections with other disciplines, including brain science, supercomputing, and artificial intelligence. Since 2016, the Central Military Commission has funded projects on military brain science, advanced biomimetic systems, biological and biomimetic materials, human performance enhancement, and “new concept” biotechnology.

Gene Editing

Meanwhile, China has been leading the world in the number of trials of the CRISPR gene-editing technology in humans. Over a dozen clinical trials are known to have been undertaken, and some of these activities have provoked global controversy. It’s not clear whether Chinese scientist He Jiankui, may have received approval or even funding from the government for editing embryos that became the world’s first genetically modified humans. The news provoked serious concerns and backlash around the world and in China, where new legislation has been introduced to increase oversight over such research. However, there are reasons to be skeptical that China will overcome its history and track record of activities that are at best ethically questionable, or at worst cruel and unusual, in healthcare and medical sciences.

But it is striking how many of China’s CRISPR trials are taking place at the PLA General Hospital, including to fight cancer. Indeed, the PLA’s medical institutions have emerged as major centers for research in gene editing and other new frontiers of military medicine and biotechnology. The PLA’s Academy of Military Medical Sciences, or AMMS, which China touts as its “cradle of training for military medical talent,” was recently placed directly under the purview of the Academy of Military Science, which itself has been transformed to concentrate on scientific and technological innovation. This change could indicate a closer integration of medical science with military research.

In 2016, an AMMS doctoral researcher published a dissertation, “Research on the Evaluation of Human Performance Enhancement Technology,” which characterized CRISPR-Cas as one of three primary technologies that might boost troops’ combat effectiveness. The supporting research looked at the effectiveness of the drug Modafinil, which has applications in cognitive enhancement; and at transcranial magnetic stimulation, a type of brain stimulation, while also contending that the “great potential” of CRISPR-Cas as a “military deterrence technology in which China should “grasp the initiative” in development.

AI + Biotech

The intersection of biotechnology and artificial intelligence promises unique synergies. The vastness of the human genome — among the biggest of big data — all but requires AI and machine learning to point the way for CRISPR-related advances in therapeutics or enhancement.

In 2016, the potential strategic value of genetic information led the Chinese government to launch the National Genebank (国家基因库), which intends to become the world’s largest repository of such data. It aims to “develop and utilize China’s valuable genetic resources, safeguard national security in bioinformatics (生物信息学), and enhance China’s capability to seize the strategic commanding heights” in the domain of biotechnology.

The effort is administered by BGI, formerly known as Beijing Genomics Inc., which is Beijing’s de facto national champion in the field. BGI has established an edge in cheap gene sequencing, concentrating on amassing massive amounts of data from a diverse array of sources. The company has a global presence, including laboratories in California and Australia.

U.S. policymakers have been concerned, if not troubled, by the company’s access to the genetic information of Americans. BGI has been pursuing a range of partnerships, including with the University of California and with the Children’s Hospital of Philadelphia on human genome sequencing. BGI’s research and partnerships in Xinjiang also raise questions about its linkage to human rights abuses, including the forced collection of genetic information from Uighurs in Xinjiang.

There also appear to be links between BGI’s research and military research activities, particularly with the PLA’s National University of Defense Technology. BGI’s bioinformatics research has used Tianhe supercomputers to process genetic information for biomedical applications, while BGI and NUDT researchers have collaborated on several publications, including the design of tools for the use of CRISPR.

Biotech’s Expansive Frontier

It will be increasingly important to keep tabs on the Chinese military’s interest in biology as an emerging domain of warfare, guided by strategists who talk about potential “genetic weapons” and the possibility of a “bloodless victory.” Although the use of CRISPR to edit genes remains novel and nascent, these tools and techniques are rapidly advancing, and what is within the realm of the possible for military applications may continue to shift as well. In the process, the lack of transparency and uncertainty of ethical considerations in China’s research initiatives raise the risks of technological surprise.

### India

#### Can’t resolve decades of historical disputes, Kashmir conflict, Ethnic and Religious tensions, crashed F-16s, Kashmir bombings etc.

#### No escalation – UQ and links are from 2020 and are about restrictions on religious gathering not military escalation

### Bioterror

#### Expertise, processes, bio samples, cell lines, distribution, and cost are all alt causes to TRIPs – only IPR can reliably scale high quality low cost medicine

Shultz and Stevens 1/14 Mark Schultz is the Goodyear Endowed Chair in Intellectual Property Law at the University of Akron School of Law, United States. Philip Stevens is Executive Director of Geneva Network., Geneva Network, "Why intellectual property rights matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19", January 14th, 2021, https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/ - BD

The real challenges

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to The Lancet: “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

John-Arne Røttingen, chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.

“Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months. Unfortunately, it is not as simple as putting a recipe on the internet”

The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, he says.

Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a range of issues need to be considered such as regulatory bottlenecks; supply chain, transport and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population.

The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official estimate of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarved by the other economic costs of the pandemic.

IP is part of the solution

Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done.

This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China’s BioKangtai (200m doses), Brazil’s FioCruz, Russia’s R-Pharm and South Korea’s SK Bioscience. Collectively, such deals will see the manufacture of 2 billion doses by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers. Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middle-income countries.

IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment.

Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The Lancet Global Health concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear inter-company competition and economies of scale.

But again, these licenses model were criticised by public health NGOs and other stakeholders, who called for the confiscation of IP rights via compulsory licensing. Time has shown such calls to be mistaken.

Conclusion

As of January 2021, there are three vaccines approved by stringent regulatory authorities with several more likely to follow in the coming months. Prices of COVID-19 vaccines vary between more expensive but complex to manufacture, and cheaper ones based on existing technologies. Companies are offering their vaccines at cost,

with pooled procurement mechanisms such as COVAX ready to leverage their enormous purchasing power to drive economies of scale and bring prices down further for developing countries, many of which will have the cost of vaccination subsidised by Overseas Development Assistance.

Meanwhile, the existence of multiple vaccines means there is no COVID-19 vaccine “monopoly”, and minimal risk of premium pricing. In fact, there is a competitive marketplace in which manufacturers are incentivised to refine and improve their vaccines – vital given the new strains of the virus which constantly emerge.

Providing COVID-19 vaccines rapidly at scale is a pressing challenge for all countries but there is no evidence that overriding intellectual property rights will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil.

Manufacturing of COVID-19 vaccines is continuing at speed, and mechanisms are gearing up to ensure a rapid global role out. Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside.

Instead of sowing division and creating major distractions at venues such as the WTO, opponents of IP should stop the rhetoric. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.

#### **IP is fundamental to collaboration and global access**

Shultz and Stevens 1/14 Mark Schultz is the Goodyear Endowed Chair in Intellectual Property Law at the University of Akron School of Law, United States. Philip Stevens is Executive Director of Geneva Network., Geneva Network, "Why intellectual property rights matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19", January 14th, 2021, https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/ - BD

IP helps not hinders R&D collaboration

The other claim frequently heard at the beginning of the pandemic was that IP poses a barrier to collaboration and knowledge-sharing, so in a time of emergency any related IP should be open licensed or pooled.

In reality, the IP system encouraged the rapid establishment of dozens of partnerships around COVID-19-19, with even commercial rivals prepared to cooperate and share capital and proprietary intellectual resources such as compound libraries. Examples of consortia between the private sector and research centres include the COVID-19-19 Therapeutics Accelerator to evaluate new and repurposed drugs and biologics, the EU-backed Swift COronavirus therapeutics REsponse, Corona Accelerated R&D in Europe (CARE) as well as dozens of bilateral agreements between companies. Indeed, the Pfizer vaccine is the result of its collaboration with BioNtech, where partners shared and combined know-how and proprietary knowledge to create the first vaccine authorized in the U.S.

Far from being a barrier to such collaborations, IP is fundamental. Because patent rights require public disclosure, they enable drug developers to identify partners with the right intellectual assets such as know-how, platforms, compounds and technical expertise. Without patents most of this valuable proprietary knowledge would be kept hidden as trade secrets, making it impossible for researchers to know what is out there.

Second, the existence of laws protecting intellectual property helps rights-holders make the decision to collaborate in the first place. By allaying concerns about confidentiality, IP enables companies to open up their compound libraries, and to share platform technology and know-how without worrying they are going to sacrifice their wider business objectives or lose control of their valuable assets.

For instance, rights holders might contribute IP that is useful for entirely different diseases to COVID-19 collaborations. IP rights and licensing ensure those rights can only be used for the agreed reason, preventing competitors freeriding to gain an unfair advantage in other areas.

As the former Director General of WIPO noted in June 2020, the main challenge at the time was “not access to vaccines, treatments or cures for COVID-19-19, but the absence of any approved vaccines, treatments or cures to have access to. The policy focus of governments at this stage should therefore be on supporting science and innovation”.

During this initial phase of the pandemic, the majority of governments followed this advice, especially by not threatening to remove IP of products yet to be invented. No government from a country with a significant life-science R&D industry, for instance, backed the WHO’s “Solidarity Call to Action” in which companies were asked to unilaterally cede IP and data related to COVID-19 to its new technology and IP pool, C-TAP. The WHO embarked on this initiative with no evidence that IP would stand in the way of R&D and access efforts, distracting efforts away from more practical initiatives that stood greater chance of success.

#### Circumvention and they don’t solve – even if they say “durable fiat”, they have not defined the scope of the plan in the 1AC so you don’t know what the plan would materially look like

Mercurio 6/24 [Simon F.S. Li Professor of Law, The Chinese University of Hong Kong, Shatin, Hong Kong. June 24, 2021. “The IP Waiver for COVID-19: Bad Policy, Bad Precedent” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/> Accessed 8/25 //gord0]

The role of intellectual property rights (IPRs) and access to medicines is contentious. On the one hand, IPRs encourage investment, innovation and the advancement of health science. On the other hand, the limited-term monopoly rights can result in artificially high prices and become a barrier to access to medicines. While the wisdom of the IPRs system has at times been tested, it has proven its value in the current COVID-19 pandemic as IPRs played a large role in the rapid (and unprecedented) development and availability of multiple vaccines. Despite the success, India and South Africa proposed that the World Trade Organization (WTO) waive IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to increase access to vaccines and other COVID-19-related technologies.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn1) The proposal, tabled at a meeting of the TRIPS Council in October 2020, calls on Members to waive IPRs relating to and having an impact on the “prevention, containment or treatment of COVID-19”.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn2) The proposal attracted support from the majority of developing country Members,[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn3) but was opposed by a handful of Members including the United States (US).[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn4) Given that consensus could not be reached within the deadline of 90 days as set out in Art. IX:3 of the Agreement Establishing the WTO, Members agreed to keep the waiver proposal on the agenda of the TRIPS Council in 2021.[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn5) On 5 May 2021, the US reversed its position and announced that it would support a waiver for COVID-19 vaccines.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn6) To be clear, this does not mean that the US supported the waiver as proposed by India and South Africa. Instead, the US has simply agreed to negotiate the perimeters of a waiver. Others, including the European Union (EU), Canada, Australia, Norway, Switzerland, the United Kingdom (UK) and even leading developing countries such as Brazil, Chile and Mexico remain opposed or lukewarm on the waiver.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn7) The US dropping opposition does not mean the concerns of other Members will simply disappear – one would hope that these nations opposed the waiver for valid reasons and did not simply blindly follow the US. Indeed, many of the above-listed Members remain unconvinced that even such a draconian step as a waiver of IPRs would accomplish the goal of increased vaccine production.[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn8) For its part, the EU continues to favour an approach which makes better use of existing flexibilities available in the TRIPS Agreement.[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn9) Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the WTO are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn10) Issues of negotiation will include the scope of the waiver. Whereas the original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn11) industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn12) (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn13) The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn14) – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn15) These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations. With so many initial divergences and as yet undiscussed issues, the negotiations at best could be completed by the time of the next WTO Ministerial Conference, scheduled to begin on 20 November 2021. There is precedent in this regard, as previous TRIPS negotiations involving IP and pharmaceuticals were not fully resolved until the days before the Ministerial Conferences (in 2003 and 2005).[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn16) There is also a chance that the negotiations will continue past the calendar year 2021. The chance for a swift negotiation diminished with the release of a revised proposal by India and South Africa on 22 May 2021. As mentioned above, the proposal contains no limit as to product coverage, scope, notification requirements or safeguards and proposes that the waiver will remain in effect for what could be an indefinite period. This was not a proposal designed to engender quick negotiations and a solution. Instead, the proposal perhaps reveals India’s and South Africa’s true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world. It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn17) The US announcement remains meaningful, however, for two reasons. First, it signals a departure from the longstanding and bipartisan support for the pharmaceutical industry, which for decades has been instrumental in setting the IP and trade agenda.[18](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn18) Second, it sends a strong signal that the US does not oppose others from waiving patent protection for vaccines. This shift may also be part of a broader and alternative strategy to increase vaccine production and distribution, whereby the US is not viewing or supporting waiver negotiations as a legal tool but more so as a threat to encourage vaccine innovators to increase production. In essence, the desired reaction would be that the IP holders increase efforts to license, transfer technology and expand manufacturing – exactly what the world needs at this time. Alan Beattie, writing in the Financial Times, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[19](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[20](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the leading vaccines using mRNA are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production. Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. The know-how and trade secrets are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up. When asked if a waiver would improve vaccine availability and equity, Watal responded: “No. It won’t. That’s clear.”[21](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn21) I share Watal’s view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that “what the proposal … will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South”[22](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn22) I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn23) IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn24) Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor. Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.