# 1NC

#### I negate the resolution resolved that: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

### Framework

#### The value criterion must be maximizing well-being for everyone.

#### There are two main reasons for this:

#### 1] Death is bad and outweighs – a] agents can’t act if they fear for their bodily security which constrains every ethical theory, b] it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life

#### 2] Existential threats outweigh – all life has infinite value and extinction eliminates the possibility for future generations – err negative, because of innate cognitive biases

GPP 17 (Global Priorities Project, Future of Humanity Institute at the University of Oxford, Ministry for Foreign Affairs of Finland, “Existential Risk: Diplomacy and Governance,” Global Priorities Project, 2017, <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>,

1.2. THE ETHICS OF EXISTENTIAL RISK In his book Reasons and Persons, Oxford philosopher Derek Parfit advanced an influential argument about the importance of avoiding extinction: I believe that if we destroy mankind, as we now can, this outcome will be much worse than most people think. Compare three outcomes: (1) Peace. (2) A nuclear war that kills 99% of the world’s existing population. (3) A nuclear war that kills 100%. (2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). I believe that the difference between (2) and (3) is very much greater. ... The Earth will remain habitable for at least another billion years. Civilization began only a few thousand years ago. If we do not destroy mankind, these few thousand years may be only a tiny fraction of the whole of civilized human history. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second.65 In this argument, it seems that Parfit is assuming that the survivors of a nuclear war that kills 99% of the population would eventually be able to recover civilisation without long-term effect. As we have seen, this may not be a safe assumption – but for the purposes of this thought experiment, the point stands. What makes existential catastrophes especially bad is that they would “destroy the future,” as another Oxford philosopher, Nick Bostrom, puts it.66 This future could potentially be extremely long and full of flourishing, and would therefore have extremely large value. In standard risk analysis, when working out how to respond to risk, we work out the expected value of risk reduction, by weighing the probability that an action will prevent an adverse event against the severity of the event. Because the value of preventing existential catastrophe is so vast, even a tiny probability of prevention has huge expected value.67 Of course, there is persisting reasonable disagreement about ethics and there are a number of ways one might resist this conclusion.68 Therefore, it would be unjustified to be overconfident in Parfit and Bostrom’s argument. In some areas, government policy does give significant weight to future generations. For example, in assessing the risks of nuclear waste storage, governments have considered timeframes of thousands, hundreds of thousands, and even a million years.69 Justifications for this policy usually appeal to principles of intergenerational equity according to which future generations ought to get as much protection as current generations.70 Similarly, widely accepted norms of sustainable development require development that meets the needs of the current generation without compromising the ability of future generations to meet their own needs.71 However, when it comes to existential risk, it would seem that we fail to live up to principles of intergenerational equity. Existential catastrophe would not only give future generations less than the current generations; it would give them nothing. Indeed, reducing existential risk plausibly has a quite low cost for us in comparison with the huge expected value it has for future generations. In spite of this, relatively little is done to reduce existential risk. Unless we give up on norms of intergenerational equity, they give us a strong case for significantly increasing our efforts to reduce existential risks. 1.3. WHY EXISTENTIAL RISKS MAY BE SYSTEMATICALLY UNDERINVESTED IN, AND THE ROLE OF THE INTERNATIONAL COMMUNITY In spite of the importance of existential risk reduction, it probably receives less attention than is warranted. As a result, concerted international cooperation is required if we are to receive adequate protection from existential risks. 1.3.1. Why existential risks are likely to be underinvested in There are several reasons why existential risk reduction is likely to be underinvested in. Firstly, it is a global public good. Economic theory predicts that such goods tend to be underprovided. The benefits of existential risk reduction are widely and indivisibly dispersed around the globe from the countries responsible for taking action. Consequently, a country which reduces existential risk gains only a small portion of the benefits but bears the full brunt of the costs. Countries thus have strong incentives to free ride, receiving the benefits of risk reduction without contributing. As a result, too few do what is in the common interest. Secondly, as already suggested above, existential risk reduction is an intergenerational public good: most of the benefits are enjoyed by future generations who have no say in the political process. For these goods, the problem is temporal free riding: the current generation enjoys the benefits of inaction while future generations bear the costs. Thirdly, many existential risks, such as machine superintelligence, engineered pandemics, and solar geoengineering, pose an unprecedented and uncertain future threat. Consequently, it is hard to develop a satisfactory governance regime for them: there are few existing governance instruments which can be applied to these risks, and it is unclear what shape new instruments should take. In this way, our position with regard to these emerging risks is comparable to the one we faced when nuclear weapons first became available. Cognitive biases also lead people to underestimate existential risks. Since there have not been any catastrophes of this magnitude, these risks are not salient to politicians and the public.72 This is an example of the misapplication of the availability heuristic, a mental shortcut which assumes that something is important only if it can be readily recalled. Another cognitive bias affecting perceptions of existential risk is scope neglect. In a seminal 1992 study, three groups were asked how much they would be willing to pay to save 2,000, 20,000 or 200,000 birds from drowning in uncovered oil ponds. The groups answered $80, $78, and $88, respectively.73 In this case, the size of the benefits had little effect on the scale of the preferred response. People become numbed to the effect of saving lives when the numbers get too large. 74 Scope neglect is a particularly acute problem for existential risk because the numbers at stake are so large. Due to scope neglect, decision-makers are prone to treat existential risks in a similar way to problems which are less severe by many orders of magnitude. A wide range of other cognitive biases are likely to affect the evaluation of existential risks.75

### C1: Disease Innovation

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

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

#### The aff crushes innovation in the pharma sector---incentivizes them to focus on non-important issues.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

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

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

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

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

### C2: China

#### The US is leading the biopharmaceuticals race – but China is close. Catching up would be a death sentence for US lead.

Gupta 21 [Gaurav; Physician, founder of the biotechnology investment firm Ascendant BioCapital; “As Washington Ties Pharma’s Hands, China Is Leaping Ahead,” Barrons; 6/11/21; <https://www.barrons.com/articles/as-washington-ties-pharmas-hands-china-is-leaping-ahead-51623438808>] Justin

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 were invented by U.S. biopharma companies, with homegrown startups 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. China saw over $28 billion 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 plan gives away sensitive biotechnology information that facilitates a China lead.

Rogin 21 [Josh; Columnist for the Global Opinions section of the Washington Post and a political analyst with CNN. Previously, he has covered foreign policy and national security for Bloomberg View, Newsweek, the Daily Beast, Foreign Policy magazine, Congressional Quarterly, Federal Computer Week magazine and Japan’s Asahi Shimbun newspaper. He was a 2011 finalist for the Livingston Award for Young Journalists and the 2011 recipient of the Interaction Award for Excellence in International Reporting. Rogin holds a BA in international affairs from George Washington University and studied at Sophia University in Tokyo. He lives in Washington, DC; “Opinion: The wrong way to fight vaccine nationalism,” The Washington Post; 4/8/21; <https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819_story.html>] Justin

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, and some countries are using the issue to advance their own strategic interests. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity.

As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October.

Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn the move would result in the United States handing over a generation of advanced research — much of it funded by the U.S. taxpayer — to our country’s greatest competitors, above all China.

In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic.

“We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.”

Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said.

But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.

Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy.

On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters.

If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, a country that strives to dominate the biotechnology field as part of its Made in China 2025 strategy. Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.

“We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School.

#### Gains are directly converted to military prowess – destroys US primacy.

Kuo 17 [Mercy A; Executive Vice President at Pamir Consulting; “The Great US-China Biotechnology and Artificial Intelligence Race,” The Diplomat; 8/23/17; <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI // Re-Cut Justin

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, **which necessitates acquiring strategic tech**nological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. Why is Chinese access to U.S. genomic data a national security concern? **Genomics** and computing research **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for biodefense.** This knowledge will lead to increasing developments at the forefront of medical countermeasures, **including vaccines**, antibiotics, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, **with potential applications in military enhancements**. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? **Gaining access to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in bio-military research.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, **malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.**

#### That causes extinction.

Yulis 17 [Max; Major in PoliSci, Penn Political Review; “In Defense of Liberal Internationalism,” Penn Political Review; 4/8/17; <http://pennpoliticalreview.org/2017/04/in-defense-of-liberal-internationalism/>] // Re-Cut Justin

Over the past decade, international headlines have been bombarded with stories about the unraveling of the post-Cold War world order, the creation of revolutionary smart devices and military technologies, the rise of militant jihadist organizations, and nuclear proliferation. Indeed, times are paradoxically promising and alarming. In relation to treating the world’s ills, fortunately, there is a capable hegemon– one that has the ability to revive the world order and traditionally hallmarked human rights, peace, and democracy. The United States, with all of its shortcomings, had crafted an international agenda that significantly impacted the post-WWII landscape. Countries invested their ambitions into security communities, international institutions, and international law in an effort to mitigate the chances of a nuclear catastrophe or another World War. The horrors and atrocities of the two Great Wars had traumatized the global community, which spurred calls for peace and the creation of a universalist agenda. Today, the world’s fickle and declining hegemon still has the ability, but not the will, to uphold the world order that it had so carefully and eagerly helped construct. Now, the stakes are too high, and there must be a mighty and willing global leader to lead the effort of diffusing democratic ideals and reinforcing stability through both military and diplomatic means. To do this, the United States must abandon its insurgent wave of isolationism and protectionism, and come to grips with the newly transnational nature of problems ranging from climate change to international terrorism.

First, the increase in intra-state conflict should warrant concern as many countries, namely in Africa and the Middle East, are seeing the total collapse of civil society and government. These power vacuums are being filled with increasingly ideological and dangerous tribal and non-state actors, such as Boko Haram, ISIS, and Al-Shabaab. Other bloody civil wars in Rwanda, Sudan, and the Congo have contributed to the deaths of millions in the past two decades. As the West has seen, however, military intervention has not been all that successful in building and empowering democratic institutions in the Far East. A civil crusade, along with the strengthening of international institutions, may in fact be the answer to undoing tribal, religious, and sectarian divisions, thereby mitigating the prospects of civil conflict. During the Wilsonian era, missionaries did their part to internationalize the concept of higher education, which has contributed to the growth of universities in formerly underdeveloped countries such as China and South Korea.[1] In addition, the teachings of missionaries emphasized the universality of humanity and the oneness of man, which was antithetical to the justifications for imperialism and the rampant sectarianism that plagued much of the Middle East and Africa.[2] Seeing that an increase in the magnitude of human casualty is becoming more of a reality due to advancements in military technology and the increasing outbreaks of civil war, international cooperation and the diffusion of norms that highlight the importance of stable governance, democracy, and human rights is the only recourse to address the rise in sectarian divides and civil conflicts. So long as the trend of the West’s desire to look inward continues, it is likely that nation states mired in conflict will devolve into ethnic or tribal enclaves bent on relying on war to maintain their legitimacy and power. Aside from growing sectarianism and the increasing prevalence of failed states, an even more daunting threat come from weapons that transcend the costs of conventional warfare.

The problem of nuclear proliferation has been around for decades, and on the eve of President Trump’s inauguration, it appeared that Obama’s lofty goal of advocating for nonproliferation would no longer be a priority of American foreign policy.[3] In addition, now that the American president is threatening to undo much of the United States’ extensive network of alliances, formerly non-nuclear states may be forced to rearm themselves. Disarmament is central to liberal internationalism, as was apparent by the Washington Naval Treaty advocated by Wilson, and by the modern CTBT treaty. The reverse is, however, being seen in the modern era, with cries coming from Japan and South Korea to remobilize and begin their own nuclear weapon programs.[4] A world with more nuclear actors is a formula for chaos, especially if nuclear weapons become mass-produced. Non-state actors will increasingly eye these nuclear sites as was the case near a Belgian nuclear power plant just over a year ago.[5] If any government commits a serious misstep, access to nuclear weapons on the behalf of terrorist and insurgent groups will become a reality, especially if a civil war occurs. States with nuclear weapons require domestic stability and strong security, which is why states such as Israel, North Korea, and Pakistan could be in serious trouble in the event of a domestic uprising or military coup. The disarmament of all states is essential for human survival, and if it is not achieved, then a world full of nuclear weapons and an international system guided by realpolitik could give rise to nuclear warfare. In today’s world, nuclear weapons leave all states virtually defenseless. But, for nuclear deproliferation to become a cornerstone of the global agenda, a pacifying and democratic power must rise to the limelight to advocate the virtues of peace, stability, and human rights.

### CASE

#### While it may sound like a good idea to reduce ITP in a vaccum, the alternative is actually much worse. Because people can build off of previous innovated drugs without patents, they can make counterfeit drugs that aren’t safe. However, because they offer them at a cheaper price, many are willing to buy them.

Tavares, an experience patent attorney focused on medical drugs 9/28 [Inês D. Tavares (Trademark and Patent Attorney at Inventa International focusing on the African continent. “Worldwide: Counterfeiting Of Fake Drugs In Africa: Current Situation, Causes And Countermeasures”. Mondaq. 28 September 2020. Accessed 8/8/21. <https://www.mondaq.com/nigeria/trademark/988968/counterfeiting-of-fake-drugs-in-africa-current-situation-causes-and-countermeasures> //Xu]

Although stopping counterfeiting is proven to be an extremely difficult challenge in Africa, several countries, along with the help of World Health Organization and other Institutions have been joining the fight. The WHO is assisting countries in developing the expertise needed to regulate drugs. One of the most important measures is the effective drug registration. Drug registration, also known as marketing authorization and product licensing, allows a country to evaluate if a specific pharmaceutical is safe for consumers to use. Through marketing licensing authorities can also assure that the manufacturing, the storage as well as the distribution of a pharmaceutical was righteously made and cared for without putting at risk the product efficiency and most importantly safety. The incursion of Anti-Counterfeiting Acts in the jurisdictions is of extreme importance to give Authorities the necessary mandate to combat counterfeiting by means of carrying out the adequate and necessary actions that will address the issue directly. A strategy that has been put in place in Tanzania and Ghana, for instance, is to instead of shutting out illegal vendors, invest in training, regulating and licensing them. Furthermore, different countries are investing in awareness campaigns to educate locals to the dangers of consuming fake pharmaceuticals. By educating the consumers they are making people more alert to the signs. Pharmaceutical red flags include, but are not limited to the following: they almost always have a cheaper price tag, they can have a different packaging or the packaging can be altered from the original, the location where the drugs are being sold is usually not reliable and trustworthy. Of course, it can be difficult, at times, to set the original product from the fake product apart. The best indicatory is usually the price point of the fake drug, being set much lower than the first generation good and the problem aggravates when the underground markets take advantage of the loopholes existing in the pharmaceutical distributing systems to channel their counterfeited drugs into the hospital, pharmacies and other distributors, which is one big reason for the education and training of consumers and health workers who are often unable to detected fake products from first generation goods. Countries like Kenya, Ghana and Nigeria have also implemented mobile telephone based consumer verification into their regulations. This system allows consumers to be protected, empowering them against fraudulent products. African countries working together is crucial, regional coordination can help control the problem at customs and at safeguarding borders. Nigeria and Cameroon had signed a cooperation agreement and compromise to sharing experiences and technical expertise to combat the problem. More recently, the Presidents of the Democratic Republic of Congo, Niger, Senegal, Togo, Uganda, Ghana and Gambia signed the Lomé initiative, dated of January 2020, a binding agreement to criminalize trafficking of falsified medicines. The Lomé initiative tackles soft spots such as the lack of regulation and weak healthcare systems. Several African countries are now trying to implement a set of measures at customs such as enabling the interception of contraband (illegal drugs as well as weapons), conduct baggage, cargo and mail inspections to travellers, protect businesses against illegal trade malpractice and enforce import and export restrictions and even prohibitions. However, and although countries are making more efforts into fighting the pharmaceutical counterfeiting problematic, the matter is extremely complex. It involves dangerous lobbies and the work of organized crime, corruption and bribery. All of these are not easy to dismantle. Several previously mentioned factors such as extreme poverty, the uneducated level of the people and lack of an effective and responsive Healthcare System aggravates the predicament. More often than not, consumers have no other alternative than to resort to drug outlets. We have to join efforts worldwide to combat fake medicine markets to thrive in Africa and other areas and Intellectual Property has an enormous role in the fight. More and more regulations are being put in place and a larger number of officials are being trained at customs to be able to detect and identify counterfeited goods, either pharmaceutical or not. Counterfeiting is a global pandemic with tragic consequences and it is crucial for countries and other institutions governmental and non-governmental to join forces and keep fighting to end the problem thus save millions of lives and jobs each year.

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

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

#### 1] List of supply shortages – there is no way the aff solves, but they decrease available vaccines.

[Laurie Garrett 21, (Columnist at Foreign Policy and former senior fellow for global health at the Council on Foreign Relations). 5/7/21, Stopping Drug Patents Has Stopped Pandemics Before, Foreign Policy, <https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/>] Justin

The vaccines aren’t easy to make. Manufacturing errors in a Maryland Emergent BioSolutions factory caused an 86 percent plummet in Johnson & Johnson vaccine supplies in early April. Complex steps in the process of isolating, purifying, preserving, storing, and delivering COVID-19 immunizations are each error-prone and require long lists of specialized chemicals and machinery.

The world is in the grips now of pipette tips shortages—used to suck out chemicals and viral samples from test tubes in key steps of vaccine making. Syringes are in short supply, prompting vaccinators to toss vaccine supplies for lack of means to administer them. The sterile containers used to hold vaccines are running out. From the earliest days of the 2020 pandemic, the sorts of protective gear and machinery vaccine researchers and makers require have been in short supply, exacerbated by trade tensions between the United States and China. Swabs used for COVID-19 testing and all aspects of equipment cleaning in sterile conditions are held up in a grotesque family dispute in Maine. There aren’t enough centrifuge tubes made worldwide to spin down cell samples. Moderna and Pfizer are constantly scrambling to find the ingredients used to make the microscopic fatty balls, called liposomes, that house the mRNA molecules and carry them safely into the bloodstream. Even the nucleic acids used to construct mRNA and a long list of special enzymes used to purify those samples are in horribly short supply, largely because their use overlaps with the manufacture of COVID-19 tests. Because such delicate chemicals and proteins must be handled at deep-freeze temperatures and transported swiftly for immediate use, the entire supply chain is vulnerable to the simplest of catastrophes: weather at an airport, a car crash that blocks truck traffic, power outages, or competition for cargo space.

Although waiving TRIPS requirements on COVID-19 vaccines is a spectacular, historic gesture, would-be generic makers worldwide will soon discover their efforts are stymied not by patents but for want of Avanti Polar Lipids’ liposome ingredients, Flexsafe RM special bags to hold liquid vaccines in bulk, phosphate-buffered saline solution, Distearoylphosphatidylcholine for liposome-making, 5’ cap for mRNA made by TriLink BioTechnologies, RNA polymerases—the list goes on, and on, and on. As the number of would-be vaccine makers grows, so will demand for thousands of such items, putting pressure on companies that are, in many cases, mom-and-pop operations. Worse, pressure on supplies critical for COVID-19 vaccine making is already resulting in a production loss of vital medicines for other diseases.

#### 2] The aff causes a scramble for limited resources by manufacturers with no experience – turns case.

Breuninger 21 [Kevin; Specialist at CNBC; “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues,” CNBC; 5/7/21; <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] Justin

“Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague letter posted on LinkedIn. “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.”

Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients.

“Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote.

He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.”

“It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote.

“Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.

#### 3] Reduced IP protections creates a rapid increase in faulty and fraudulent vaccines

Norquist 21 Grover Norquist (president of Americans for Tax Reform), 5/21/21, Biden is wrong to let other nations seize US intellectual property, The Hill, https://thehill.com/opinion/white-house/554629-biden-is-wrong-to-let-other-nations-seize-american-intellectual-property/SJKS

Upon taking office, Biden promised to hold China accountable. In a speech weeks after the inauguration, Biden [vowed](https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/02/04/remarks-by-president-biden-on-americas-place-in-the-world/) to “push back on China’s attack on human rights, intellectual property and global governance.” To onlookers that day, Biden was promising to build on former [President Trump](https://thehill.com/people/donald-trump)’s [progress in holding China accountable](https://www.cnbc.com/2020/01/16/us-china-trade-deal-intellectual-property-protection-benefits-beijing.html). By backing the IP waiver, Biden will [ignore warnings](https://www.fbi.gov/news/pressrel/press-releases/peoples-republic-of-china-prc-targeting-of-covid-19-research-organizations) from the FBI that China was targeting COVID-19 research. China has long [pushed](https://www.tandfonline.com/doi/abs/10.1080/10192577.2016.1201261?journalCode=rplr20) to weaken global IP protections, known as TRIPS (Trade-Related Aspects of Intellectual Property Rights). Rather than surrendering on IP rights, the Biden administration should reduce protectionist trade restrictions imposed by other nations on COVID-19 products and encourage investments into vaccine manufacturing capacity that mirror Trump’s [Operation Warp Speed](https://public3.pagefreezer.com/browse/HHS%20%E2%80%93%C2%A0About%20News/20-01-2021T12:29/https:/www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html). Seizing the trade secrets and IP of American COVID-19 manufacturers will do nothing to help fight the pandemic. Criminal syndicates all over the world have already [taken advantage](https://www.interpol.int/News-and-Events/News/2020/Global-operation-sees-a-rise-in-fake-medical-products-related-to-COVID-19) of the crisis to market fake COVID-19 tests, fake personal protective equipment and [fake vaccines](https://slate.com/technology/2021/05/counterfeit-covid-vaccines-mexico.html). Biden will make the problem worse. Foreign countries could see a flood of fraudulent vaccines from criminal organizations and from generic manufacturers that struggle to get the formula right. The case of [Emergent BioSolutions](https://www.nytimes.com/2021/03/31/us/politics/johnson-johnson-coronavirus-vaccine.html) — a Maryland-based manufacturer that contaminated 15 million doses of the Johnson and Johnson vaccine — shows that the manufacturing process is complex and requires extensive quality checks.

#### Reducing IPR Doesn’t Solve.

Younging 10 “Intergovernmental Committee On Intellectual Property And Genetic Resources Traditional Knowledge And Folklore” Seventeenth Session Geneva, December 6-10, 2010 Wipo Indigenous Panel On The Role Of The Public Domain Concept: Experiences In The Fields Of Genetic Resources, Traditional Knowledge And Traditional Cultural Expressions: Experiences From Canada Document prepared by Mr. Gregory Younging [Creative Rights Alliance, Kelowna, Canada, Opaskwayak Cree Nation-Canada] <https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_5_a.pdf> SM

Under the IPR system, knowledge and creative ideas that are not “protected” are in the Public

Domain (i.e. accessible by the public). Generally, Indigenous peoples have not used IPRs to protect their knowledge; and so TK is often treated as if it is in the Public Domain – without regard for Customary Laws. Another key problem for TK is that the IPR system’s concept of the Public Domain is based on the premise that the author/creator deserves recognition and compensation for his/her work because it is the product of his/her genius; but that all of society must eventually be able to benefit from that genius. Therefore, according to this aspect of IPR theory, all knowledge and creative ideas must eventually enter the Public Domain. Under IPR theory, this is the reasoning behind the time period limitations associated with copyright, patents and trademarks.

The precept that all Intellectual Property, including TK, is intended to eventually enter the Public Domain is a problem for Indigenous peoples because Customary Law dictates that certain aspects of TK are not intended for external access and use in any form. As a response to this, there have been circumstances where indigenous people have argued that some knowledge should be withdrawn from circulation and that for specific kinds of knowledge, protection should be granted in perpetuity. 29 Examples of this include, sacred ceremonial masks, songs and dances, various forms of shamanic art, sacred stories, prayers, songs, ceremonies, art objects with strong spiritual significance such as scrolls, petroglyphs, and decorated staffs, rattles, blankets, medicine bundles and clothing adornments, and various sacred symbols, designs, crests, medicines and motifs. However, the present reality is that TK is, or will be, in the Public Domain (i.e., the IPR system overrides Customary Law.)

Certain aspects of TK should not enter the public domain (as deemed under Customary Law) and should remain protected as such into perpetuity, which could be expressed as a form of “Indigenous private domain.” (Younging 2007). Indigenous peoples’ historical exclusion from the broad category of ‘public’ feeds part of the differences in objectives. Indigenous peoples also present different perceptions of knowledge, the cultural and political contexts from which knowledge emerges, and the availability, or perceived benefits of the availability, of all kinds of cultural knowledge. 30

Copyright Case Study: The Cameron Case

In 1985 the Euro-Canadian author Anne Cameron began publishing a series of children’s books though Harbour Publications based on Westcoast Indigenous traditional stories. These books include: The Raven, Raven and Snipe, Keeper of the River, How the Loon Lost Her Voice, Orca’s Song, Raven Returns the Water, Spider Woman, Lazy Boy and Raven Goes Berrypicking. Cameron had been told the traditional stories by Indigenous storytellers and/or had been present at occasions where the stories were recited. The original printing of the books granted Anne Cameron sole authorship, copyright and royalty beneficiary, and gave no credit to the Indigenous origins of the stories. As the discourse around Indigenous cultural appropriation emerged in the 1990s, Cameron’s books came under severe Indigenous criticism; not only on the grounds of cultural appropriation, but the Indigenous TK holders asserted that some of the stories and aspects of the stories were incorrect.

This led to a major confrontation with Indigenous women authors at a women writer’s conference in Montreal in 1990. At the end of the confrontation Cameron agreed not to publish any more Indigenous stories in the series: however, she did not keep her word and the books continued to be reprinted and new books in the series continued to be published (Armstrong and Maracle1992). Some minor concessions have been made in subsequent reprints of books in the series and new additions. Reprints of the books that were produced after around 1993/94 contained the disclaimer: “When I was growing up on Vancouver Island I met a woman who was a storyteller. She shared many stories with me and later gave me permission to share them with others… the woman’s name was Klopimum.” However, Cameron continued to maintain sole author credit, copyright and royalties payments. In a further concession, the 1998 new addition to the series T’aal: the One Who Takes Bad Children is co-authored by Anne Cameron and the Indigenous Elder/storyteller Sue Pielle who also shares copyright and royalties.

Patent Case Study: The Igloolik Case

An example of the failure of the Patent Act In Canada to respond to Inuit designs is the Igloolik Floe Edge Boat Case.31 A floe edge boat is a traditional Inuit boat used to retrieve seals shot at the floe edge (the edge of the ice floe), to set fishing nets in summer, to protect possessions on sled when travelling by snowmobile or wet spring ice, and to store hunting or fishing equipment. In the late 1980’s the Canadian government sponsored the Eastern Arctic Scientific Research Center to initiate a project to develop a floe edge boat that combined the traditional design with modern materials and technologies. In 1988 the Igloolik Business Association (IBA) sought to obtain a patent for the boats. The IBA thought that manufactured boats using the floe edge design would have great potential in the outdoor recreation market. To assist the IBA with its patent application the agency, the Canadian Patents and Developments Limited (CPDL) initiated a pre-project patent search that found patents were already held by a non-Inuit company for boats with similar structures. The CPDL letter to the IBA concluded that it was difficult for the CPDL to inventively distinguish the design from previous patents and, therefore, the IBA patent would not be granted. The option of challenging the pre-existing patent was considered by the IBA, however, it was decided that it would not likely be successful due to the high financial cost and risk involved in litigation.

Trademark Case: The Snumeymux Case

As most Indigenous communities are far behind in terms of establishing businesses most trademarking of TK involves a non-Indigenous corporation trademarking an Indigenous symbol, design or name. Again, many cases could have been examined in this section but only two have been chosen: one case involving the Snumeymux Band trade marking petroglyphs through the Canadian Patent Office, and one involving an international corporation’s patent licence being the subject of an intense international Indigenous lobbying effort.

The Snumeymux people have several ancient petroglyphs located off their reserve lands near False Narrows on Gabriola Island, BC. In the early 1990s non-Indigenous residents of Gabriola Island began using some of the petroglyph images in coffee shops and various other business logos. In the mid-1990s the Island’s music festival named itself after what had become the local name of the most well known petroglyph image, the dancing man. The Dancing Man Music Festival then adopted the image of the dancing man as the festival logo and used it on brochures, posters, advertisements and T-shirts.

The Snuneymux Band first made unsuccessful appeals to the festival, buisnesses and the Gabriola community to stop using the petroglyph symbols. In 1998 the Snuneymux Band hired Murry Brown as legal counsel to seek protection of the petroglyphs (Manson-2003). At a 1998 meeting with Brown, Snuneymux Elders and community members on the matter, The Dancing Man Festival and Gabriola business’ and community representatives were still defiant that they had a right to use the images from the petroglyphs (Brown-2003).

On the advice of Murry Brown, The Snuneymux Band filed for a Section 91(n) Public Authority Trademark for eight petroglyphs and was awarded the trademark in October of 1998 (Brown2003). The trademark protects the petrogylphs from “all uses” by non-Snuneymux people and, therefore the Dancing Man Festival and Gabriola Island business and community representatives were forced to stop using images derived from the petroglyphs. In the Snuneymux case the petroglyphs were trademarked for “defensive” purposes. The Snuneymux case represents an innovative use of the IPR system that negotiated within the systems limitations and found a way to make it work to protect TK.

Case Studies Summary

The case studies have shown that serious conflicts exist between the IPR and TK systems and lead to the conclusion that it constitutes a major problem which Indigenous peoples must work out with the modern states they are within and the international community. In contrast to Eurocentric thought, almost all Indigenous thought asserts that property is a sacred ecological order and manifestations of that order should not be treated as commodities.32 It is clear that there are pressing problems in the regulation of TK. It is also clear that IPR system and other Eurocentric concepts do not offer a solution to some of the problems. There have been cases of Indigenous people using the IPR system to protect their TK. However, the reality is that there are many more cases of non-Indigenous people using the IPR system to take ownership over TK using copyright, trademark, patents and the Public Domain. In many such cases this had created a ridiculous situation whereby Indigenous peoples cannot legally access their own knowledge. A study undertaken on behalf of the Intellectual Property Policy Directorate (IPPD) of Industry Canada and the Canadian Working Group on Article 8(j) concluded: “There is little in the cases found to suggest that the IP system has adapted very much to the unique aspects of Indigenous knowledge or heritage. Rather, Indigenous peoples have been required to conform to the legislation that was designed for other contexts and purposes, namely western practices and circumstances. At the same time, there is little evidence that these changes have been promoted within the system, i.e., from failed efforts to use it that have been challenged” (IPPD-2002). Such conclusions, along with other conclusions being drawn in other countries and international forums, and the case study examples discussed, appear to support the argument that new systems of protection need to be developed. Sui Generis models based on and/or incorporating Customary Laws have been proposed and developed in many countries and are being discussed in the WIPO IGC.

Gnaritas Nullius (Nobody’s Knowledge)

Just as Indigenous territories were declared as Terra Nullius in the colonization process, so too has TK been treated as Gnaritas Nullius (Nobody’s Knowledge) by the IPR system and consequently flowed into the public domain along with Western knowledge. This has occurred despite widespread Indigenous claims of ownership and breech of Customary Law. The problem is that advocates for the public domain seem to see knowledge as the same concept across cultures, and impose the liberal ideals of freedom and equality to Indigenous peoples knowledge systems. Not all knowledge has the same role and significance within diverse epistemologies, nor do diverse worldviews all necessarily incorporate a principle that knowledge can be universally accessed. Neither can all knowledge fit into a Western paradigms and legal regimes. A central dimension of Indigenous knowledge systems is that knowledge is shared according to developed rules and expectations for behavior within frameworks that have been developed and practiced over centuries and millennium. Arguments for a public domain of Indigenous knowledge again reduces the capacity for Indigenous control and decision making (Anderson 2010) and can not be reasonably made outside the problematic frameworks of the colonization of TK and Gnaritas Nullius.