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## pharma da

#### Pharma innovation is high now and strong IP protection are the only incentive for drug innovation – the plan decks that

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work>

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### **Innovation is necessary to solve future pandemics, antimicrobial diseases, and bioterror.**

Marjanovic and Fejiao 20 Marjanovic, Sonja, and Carolina Feijao. SonjaMarjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020).

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions. Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.

#### Covid magnifies the bioterror threat which risks extinction

Walsh 20, Bryan Walsh, 5-14-2020, "The coronavirus pandemic reawakens bioweapon fears," Axios, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released. Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science. That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity. That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection. Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people. COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade. "Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability." While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab. The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

## biotech da

#### Continued biotech innovation is key to cutting emissions by half and prevent the 2 degree tipping point

Heath 21, Michelle Mcmurry-Heath May 21, 2021, 5-21-2021, "To help solve climate change, look to the biosciences," STAT, https://www.statnews.com/2021/05/21/climate-change-solutions-from-biosciences/ tw

President Biden’s pledge to cut U.S. greenhouse gas emissions in half by 2030 is an admirable and ambitious undertaking. It’s nearly double the goal set by President Obama in 2015. And it establishes the United States as a world leader in battling climate change. The biosciences, including biotechnology, will play a pivotal role in the fight against climate change. It is already leading the way on several fronts. According to a report from BIO, the organization I work for, the biotech industry’s green initiatives could mitigate the equivalent of 3 billion tons of carbon dioxide every year by 2030, or about half of the country’s annual CO2 emissions. Food consumption — and production — is central to human existence. Global food production accounts for one-quarter of greenhouse gas emissions. A recent report from an international team of researchers concluded that even if all other fossil fuel emissions were eliminated, emissions from food production alone would prevent us from reaching a key goal of the climate change agreement signed in Paris: preventing the global temperature from rising more than 2 degrees Celsius. Halting food production isn’t an option, so biotech companies are helping farmers become part of the climate solution. Take, for example, Boston-based Joyn Bio. It is [are] engineering bacteria that pull nitrogen directly from the atmosphere. These microbes then pass the nitrogen to crops like wheat and corn, reducing the need to make, transport, and apply nitrogen fertilizers, which reduces greenhouse gas emissions. Biotechnology can also help protect food from climate change. As fungal and bacterial infections accelerated by human-driven environmental disturbances threaten to wipe out Cavendish bananas, Tropic Biosciences in the United Kingdom is using CRISPR gene-editing technology to engineer infection-resistant bananas. Fuel is another target for biotechnology. Transportation accounts for the highest percentage of U.S. greenhouse gas emissions. While electric cars are gaining popularity, and the $174 billion allocated to support the transition to electrics in Biden’s American Jobs Plan is important, biofuels — which are carbon neutral — will be needed to help reduce emissions in transportation and need comparable support. The biotech company Synthetic Genomics, for instance, is utilizing saltwater algae, which [and] convert sunlight and carbon dioxide into biomass, to make sustainable auto fuel. By 2025, 10,000 barrels of the algal biofuel could be produced per day for commercial use. Biotech firms are already stepping up. Companies like Neste, Gevo, and World Energy are using everything from algae to used or wasted cooking oil to create sustainable jet fuels. LanzaTech recycles carbon from industrial emissions and other sources and turns it into aviation fuel — and has recently partnered with other corporations to bring that fuel to market for commercial airline use. With help from biotechnology, the U.S. can achieve the climate change goals outlined by the Biden administration and the Paris Agreement. Human progress and technology got us into this mess. That same ingenuity can help get us out.

#### Biotech patents are high now and solving warming but waivers set an alarming precedent – the threat is enough to kill investment and devastate international cooperation

Brand 21, Melissa Brand, 5-26-2021, "TRIPS IP Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors," IPWatchdog, https://www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/ tw

While the discussions around waiving intellectual property (IP) rights set forth in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are currently (and somewhat amorphously) limited to COVID-19 related drug and medical products, it is probably shortsighted to ignore the implications for other technologies critical to sustaining our environment and advancing a more healthful world. In fact, if we want to ensure continued investment in these technologies, we should be very concerned about the message conveyed by the international political tide: if you overcome a challenging scientific problem and your solution has the potential to save lives, be prepared to be subjected to intense political pressure and to potentially hand over your technology without compensation and regardless of the consequences. The biotech industry is making remarkable advances towards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course we dispute this notion), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) Katherine Tai was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensation, and no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietary know-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone [which] could be devastating to voluntary international collaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation raised over $1 billion in investment in the second quarter of 2019 alone. If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels. It is quite reasonable to be worried about the broad implications of a TRIPS IP waiver precedent. International campaigns to weaken IP rights seem to be taking hold in U.S. domestic policy. The TRIPS IP waiver discussions will not conclude in the near term and will not yield more shots in people’s arms. This is not even truly disputed, as our own administration acknowledges that the goal here is technology transfer abroad. Given the signaling that our Administration believes waiving IP rights is an appropriate measure to end global crises, it is proper to worry that facets of the biotech sector addressing climate change may be next on the chopping block.

#### Climate change is a threat multiplier and causes extinction

Torres 16, Phil Torres, 7-22-2016, "Op-ed: Climate Change Is the Most Urgent Existential Risk," Future of Life Institute, https://futureoflife.org/2016/07/22/climate-change-is-the-most-urgent-existential-risk/?cn-reloaded=1

Climate change and biodiversity loss may pose the most immediate and important threat to human survival given their indirect effects on other risk scenarios. As such, they have the capacity to raise or lower the probability of other risks scenarios unfolding. Ask yourself the following: are wars more or less likely in a world marked by extreme weather events, megadroughts, food supply disruptions, and sea-level rise? Are terrorist attacks more or less likely in a world beset by the collapse of global ecosystems, agricultural failures, economic uncertainty, and political instability? Both government officials and scientists agree that the answer is “more likely.” For example, the current Director of the CIA, John Brennan, recently identified “the impact of climate change” as one of the “deeper causes of this rising instability” in countries like Syria, Iraq, Yemen, Libya, and Ukraine. Similarly, the former Secretary of Defense, Chuck Hagel, has described climate change as a “threat multiplier” with “the potential to exacerbate many of the challenges we are dealing with today — from infectious disease to terrorism.” The Department of Defense has also affirmed a connection. In a 2015 report, it states, “Global climate change will aggravate problems such as poverty, social tensions, environmental degradation, ineffectual leadership and weak political institutions that threaten stability in a number of countries.” Scientific studies have further shown a connection between the environmental crisis and violent conflicts. For example, a 2015 paper in the Proceedings of the National Academy of Sciences argues that climate change was a causal factor behind the record-breaking 2007-2010 drought in Syria. This drought led to a mass migration of farmers into urban centers, which fueled the 2011 Syrian civil war. Some observers, including myself, have suggested that this struggle could be the beginning of World War III, given the complex tangle of international involvement and overlapping interests. The study’s conclusion is also significant because the Syrian civil war was the Petri dish in which the Islamic State consolidated its forces, later emerging as the largest and most powerful terrorist organization in human history. The point is that climate change and biodiversity loss could very easily push societies to the brink of collapse. This will exacerbate existing geopolitical tensions and introduce entirely new power struggles between state and nonstate actors. At the same time, advanced technologies will very likely become increasingly powerful and accessible. As I’ve written elsewhere, the malicious agents of the future will have bulldozers rather than shovels to dig mass graves for their enemies. If the conversation were to end here, we’d have ample reason for placing climate change and biodiversity loss at the top of our priority lists. But there are other reasons they ought to be considered urgent threats. I would argue that they could make humanity more vulnerable to a catastrophe involving superintelligence and even asteroids. Now imagine trying to solve these problems amidst a rising tide of interstate wars, civil unrest, terrorist attacks, and other tragedies? The societal stress caused by climate change and biodiversity loss will almost certainly compromise important conditions for creating friendly AI, such as sufficient funding, academic programs to train new scientists, conferences on AI, peer-reviewed journal publications, and communication/collaboration between experts of different fields, such as computer science and ethics.

## India da

#### India is building it’s relations with the West on the bedrock of new economic ties­­­­­---that’s key to counterbalancing China in the region

Mohan 21 C. Raja Mohan [director of the National University of Singapore’s Institute of South Asian Studies.],3-19-2021, "India Romances the West," Foreign Policy, https://foreignpolicy.com/2021/03/19/india-modi-west-quad-china-biden-non-aligned/ , accessed 8/8/2021 EH and Brett

In affirming that the “Quad has come of age” at the first-ever summit of the Quadrilateral Dialogue with the United States, Japan, and Australia last week, Indian Prime Minister Narendra Modi has sent an unmistakable signal that India is no longer reluctant to work with the West in the global arena, including in the security domain. The country’s new readiness to participate in Western forums marks a decisive turn in independent India’s world view. That view was long defined by the idea of nonalignment and its later avatar, strategic autonomy—both of which were about standing apart from, if not against, post-World-War-II Western alliances. But today—driven by shifting balance of power in Asia, India’s clear-eyed view of its national interest, and the successful efforts of consecutive U.S. presidents—India is taking increasingly significant steps toward the West. The Quad is not the only Western institution with which India might soon be associated. New Delhi is set to engage with a wider range of Western forums in the days ahead, including the G-7 and the Five Eyes. Britain has invited India to participate in the G-7 meeting in London this summer, along with other non-members Australia and South Korea. Although India has been invited to G-7 outreach meetings—a level or two below the summits—for a number of years, the London meeting is widely expected to be a testing ground for the creation of a “Democracy Group of Ten,” or D-10. In Washington today, there are multiple ideas for U.S.-led technology coalitions to reduce the current Western dependence on China. Two initiatives unveiled at the Quad summit—the working group on critical technologies, and the vaccine initiative to supply Southeast Asia—underline the prospects for an Indian role in the trusted technology supply chains of the United States and its partners. Along with Japan, India also joined a meeting of the Five Eyes—the intelligence-sharing alliance between the United States, Canada, Britain, Australia, and New Zealand— in October 2020 to discuss ways to give law enforcement agencies access to encrypted communications on platforms such as WhatsApp and Telegram. Five Eyes is a tightly knit alliance, and it is unlikely India will be a member any time soon. But it is very much possible to imagine greater consultations between the Five Eyes and the Indian intelligence establishment.To be sure, India’s engagement with Western institutions is not entirely new. India joined the British-led Commonwealth in 1947, but only after India’s first prime minister, Jawaharlal Nehru, made sure the forum was stripped of any security role in the postwar world. Refusing to join military alliances was a key plank of India’s policy of non-alignment. Nehru turned to the United States when his policy of befriending China and supporting its sensitivities collapsed by the end of the 1950s. Facing reverses in a military conflict with China on the long and contested border in 1962, Nehru sought massive defense assistance from U.S. President John Kennedy. With the deaths of both Kennedy and Nehru soon after, the prospects for strategic cooperation between New Delhi and Washington receded quickly. The 1970s saw India drift away from the West on three levels. On the East-West axis, it drew closer to the Soviet Union. On the North-South axis, it became the champion of the Third World. This was reinforced by the sharply leftward turn of India’s domestic politics and a deliberate severing of commercial cooperation with the West. Many concluded in the 1970s that anti-Americanism was part of India’s genetic code. After all, India voted more often against the United States at the United Nations during the Cold War than even the Soviet Union. The idea that India is irreconcilably opposed to the United States was the dominant assessment in both country’s capitals. Most scholars of Indian foreign policy assumed that come what may—at home or abroad—India would forever be alienated from the West. But the story of India’s international relations over the last three decades has been one of a slow but definite advances in cooperation with the United States and the West. The Quad summit is not only a culmination of that long trajectory, but also a major step up. It was the reform of the Indian economy at the end of the Cold War, along with the collapse of the Soviet Union as India’s superpower partner, that created the basis for the renewal of ties between New Delhi and Washington. But even as expanding commercial ties began to stabilize and deepen the bilateral relationship in the 1990s, Washington’s activism on Kashmir and its eagerness to denuclearize India made matters difficult for New Delhi. Beset with domestic turbulence and an era of weak coalition governments, New Delhi embarked on a hedging strategy by joining the Russian initiative for a so-called strategic triangle with Moscow and Beijing that eventually evolved into the BRICS Forum after Brazil and South Africa joined. U.S. President George W. Bush, however, revolutionized U.S. policy on India in the 2000s by discarding Washington’s mediating impulse on Kashmir, decoupling engagement with New Delhi from that with Islamabad, and resolving the dispute over non-proliferation. Bush recognized that India is critical for the construction of a stable balance of power in Asia as the continent was being transformed by the rapid rise of China. But just when Washington was ready to transform relations with New Delhi, India was paralyzed by self-doubt. If then-Prime Minister Atal Bihari Vajpayee boldly called India and the United States “natural allies” in 1998—at a time when no one seemed interested in Washington—his successor, Manmohan Singh, reverted to type. His government began to reinvent non-alignment, keep distance from the United States, and double down on the principle of strategic autonomy. Even as Indian-Chinese tensions multiplied after 2008—when the global financial crisis seemed to have convinced the Chinese leadership that the United States was in terminal decline, with the consequence that Beijing adopted a more assertive posture towards its neighbors—the Singh government continued to hedge against U.S. power. Modi, who became prime minister in 2014, began to reverse New Delhi’s resistance to a deeper partnership with Washington. His affirmation in his 2016 address to the U.S. Congress that India’s “historic hesitations” to engage the United States were over was not just a rhetorical flourish. Modi resolved the remaining issues that had prevented implementation of the historic 2008 Indian-U.S. nuclear deal, renewed the 2005 agreement for defense cooperation, and signed the so-called foundational defense agreements that have facilitated interoperability between the two country’s armed forces. He widened the annual bilateral Malabar exercises to include Japan in 2015 and Australia in 2020, helped revive the dormant Quad in 2017, came up with his own version of the Free and Open Indo-Pacific strategy in 2018, and joined the Quad summit in 2021. Beyond the relationship with the United States, Modi also revived India’s strategic interest in the Commonwealth, strengthened ties with the European Union, and joined the European Alliance for Multilateralism. He sought to make India part of the solution to mitigating climate change, supported “multi-stakeholderism” in global internet governance, initiated the International Solar Alliance and the Indo-Pacific maritime partnership with France, and is poised to lay the foundations for a substantive strategic partnership with British Prime Minister Boris Johnson when they meet in India next month. Every one of these moves was against the predominant instincts of India’s political class, bureaucratic establishment, and foreign-policy community. Two factors have facilitated this. First, Modi carried little of the anti-Western ideological baggage of the nationalists who thrive in his own party or the political left and center that prefer to keep a safe distance from Washington. Modi’s judgement that India needs a more productive relationship with the United States and the West is rooted in the simple calculus of national interest rather than any involved reasoning.

#### The TRIPS waiver sets the stage for India to use forced tech transfer to secure vaccines---that decks relations

Yogesh Pai & Prashant Reddy Thikkavarapu 21, Dr. Yogesh Pai has a PhD from the Inter-University Centre for IPR Studies, CUSAT, Kochi, in the area of Regulation of Standard-Essential Patents in India. Prashant Reddy Thikkavarapu Assistant Professor, National Academy of Legal Studies & Research (NALSAR) University of Law,. Hyderabad. Scrolli.in, Jun 01, 2021. “Even if WTO waives IP on vaccines, India will face challenge translating this into mass production” <https://scroll.in/article/996079/even-if-wto-waives-ip-on-vaccines-india-will-face-challenge-translating-this-into-mass-production> brett

With the United States agreeing to text-based negotiations on the revised Intellectual Property Rights waiver proposal jointly submitted by India and South Africa at the World Trade Organisation, the European Union remains the last major power opposing this proposal.

While we await the results of possibly lengthy text-based negotiations, it is necessary for the government of India to come out with a white paper explaining how exactly it intends to operationalise a possible IP waiver for vaccines, if and when such a waiver comes into effect.

The aim of such an exercise should be to explain to the world the manner in which this waiver will translate into the mass production of vaccines to meet the immediate medical needs of the developing world.

The initial wisdom among the proponents of the waiver is based on an assumption that a waiver will remove the legal barriers to production of vaccines. But as is widely acknowledged by most experts, developing countries will not be able to reverse-engineer these Covid-19 vaccines on their own. They will require active technology transfer from vaccines developers in the West before they can begin manufacture of any vaccines. These challenges are more practical than legal. Tech-transfer challenge For starters, even if the IP waiver does come into effect, unless the tech-owning vaccine producers residing abroad (i.e. beyond India’s legal limits) are forced under their respective domestic law to part with critical know-how and physical inputs (for example, cell lines), a waiver in itself will not translate into technology transfer in favour of firms willing to produce vaccines in India. Thus the Pfizer/BioNtech and Moderna’s mRNA vaccine technologies, which are currently not produced in India, may still remain inaccessible under the waiver, unless countries such as the U.S. where these firms primarily reside engage in forced technology transfer under their domestic laws. It is very unlikely that the Biden administration will force American companies to transfer their technology to Indian companies for no remuneration. The domestic political costs of such a policy would be too high for the Biden administration. A domestic policy option for India is to threaten Western vaccine makers in India with punitive action against their existing patents for other products if they fail to voluntary transfer technology to Indian companies. Such a move towards forced technology transfer is the policy equivalent of throwing a grenade at India’s trade relations with the West without solving the problem of access to technology.

Presuming India does enact a legislative measure to force technology transfer, it is still not clear how a legal obligation to transfer technology to new firms willing to produce vaccines will lead to actual vaccine production.

#### US-India economic ties are key to strategic co-operation

Gupta 20, Anubhav Gupta is the associate director of the Asia Society Policy Institute in New York. WPR, March 5, 2020. “Despite the Trump-Modi ‘Love,’ Trade Is Still the Weak Link in U.S.-India Relations” <https://www.worldpoliticsreview.com/articles/28579/despite-the-trump-modi-love-trade-is-still-the-weak-link-in-us-india-relations> brett

Despite winning a substantial mandate in elections last year, Modi’s inclination has been to double down on a feckless approach to trade and to push a Hindu-nationalist social agenda that endangers internal stability. India’s fast-growing economy helped solidify the U.S.-India partnership after decades of bilateral aloofness during the Cold War. Without a more open, market-oriented economy, India’s growth trajectory will decline, undermining the economic foundation of the relationship as well as India’s future capabilities, and in turn, India’s utility as a partner in the region.

In the aftermath of Trump’s visit, some analysts have dismissed the trade tensions as a minor hurdle and pointed to the strength of defense ties as reassurance, arguing that the cause of paramount importance—a strategic partnership to deal with a rising China—is progressing unabated. But there is no guarantee that trade differences can continue to be compartmentalized when two economic nationalists are in charge. It also remains an open question whether growing defense sales are taking place within a truly strategic framework or simply on a transactional basis for both sides. Most importantly, it assumes that economic relations are not part of the strategic puzzle.

This is evident in the decision by Trump to leave the Trans-Pacific Partnership shortly after winning election, and by Modi to abandon the Regional Comprehensive Economic Partnership. If the U.S.-India strategic imperative is to manage China’s rise and boost their own engagement and presence in the region, these twin actions, driven by economic nationalism, were self-inflected blunders of the highest order.

Without a vibrant commercial relationship and a constructive approach to trade that is anchored in the Free and Open Indo-Pacific strategy, the United States and India will impede their own strategic endgame for the region. For this reason, the absence of a trade deal last week makes any celebrations of a U.S.-India partnership that is “stronger than ever before” ring a little hollow.

#### Indian ocean goes nuclear---India’s role is key to prevent it.

Gamage 17 (Rajni Gamage is a senior analyst with the Maritime Security Programme at the Institute of Defence and Strategic Studies, S. Rajaratnam School of International Studies, Nanyang Technological University, Singapore., 11/5/17, “Why the Indian Ocean Must Not Become Like the South China Sea”, https://nationalinterest.org/feature/why-the-indian-ocean-must-not-become-the-south-china-sea-23028?page=0%2C2)

Rising Strategic Uncertainty in the Indian Ocean The pursuit of contesting regional orders by major powers has engendered a strategic environment of uncertainty and mistrust in the Indo-Pacific. As geopolitical developments at land and sea feed off one another, the maritime domain has been marked as the latest theater of war. These dynamics have been most evident in the East and South China Seas, where the complexity of issues at hand is telling. A case in point is China’s construction of military facilities on artificial islands proximate to disputed maritime areas, against a backdrop of contesting interpretations of international law. As regional and extra-regional states face a rising China on all fronts, a climate of strategic anxiety prevails in anticipation of its potential impact on the existing rules-based international order. Such anxieties inevitably spill over into the Indian Ocean Region and manifest in ways unique to that part of the world. A rising India with aspirations to global-power status finds its regional dominance challenged by China’s two-ocean strategy and Belt and Road Initiative. In the maritime realm, India’s response comprises internal naval and port modernization, and increased naval engagements and exercises with neighboring littorals and external powers that have major stakes in the region. This has not, however, had any noticeable effects in tempering regional anxieties. Heavy maritime traffic in increasingly congested regional waters operate alongside this tense backdrop. The risk that various surface vessels could collide—whether naval or commercial—and the risk of submarine accidents is on the rise. A number of regional and extra-regional states have forward-deployed their navies in the Indian Ocean, independently or as part of various task forces. There have already been several maritime accidents involving warships and air crashes in the Persian Gulf and the northern Arabian Sea between regional and extra-regional navies—some of which escalated politically. The Iranian Navy, for instance, has confronted its smaller neighbors and the U.S. Navy by conducting high-speed naval maneuvers and missile firings, and it has used drones to shadow U.S. naval assets. Late last year, an Indian submarine attempted to enter into waters close to Gwadar Port and was reportedly repelled by the Pakistan Navy. Miscommunications and misperceptions are likely to result from such incidents and could escalate very fast to negative political and military expressions. It is against this setting that a code of conduct (COC) for the Indian Ocean was first proposed.

# Case

## Evergreening

#### No impact to secondary patents innovation rn is still hella high, look to covid or the mrna hiv vaccines

#### Turn: IPRs are key to providing quality access drugs – that outweighs because bad quality drugs -> death.

Lybercker 16, Kristina M. L. Acri NéE Lybecker, 6-27-2016, "Counterfeit Medicines and the Role of IP in Patient Safety," IPWatchdog, https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/

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Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France.  Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals.   UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels;  there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that **10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.**[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. **Without the assurance of quality medicines, access is meaningless**.

#### The aff is insufficient: there are additional causes to lack of access to medicine that ip reductions don’t solve. Lybeck continues,

Lybecker continues Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need:  inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives. If the United Nations is serious about addressing the critical need for access to medicines, the Secretary General must come to terms with the reality surrounding the challenges of access to medicine. Although the international patent system may be in need of improvement, it is overly simplistic to blame drug patents, international trade agreements and the global pharmaceutical industry for the access problem. The problem is far more nuanced and complicated than portrayed by the High Level Panel. As the WHO, OECD and Senator Hatch recognize, intellectual property rights (iprs) are part of the solution. To truly address the access problem, we must move beyond blaming IPRs and begin the difficult work of grappling with structural deficiencies and poverty.

## India

#### Limited manufacturing and poor distribution infrastructure outweigh their evidence – its something patent reductions can’t solve.

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

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