## 1

#### We are on pace to cut emissions by half in 2030 and prevent 2 degree tipping point, but continued biotech innovation is key

**Mcmurry-Health 5-21** 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/> //Nato

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. But reaching the president’s target in just under 10 years is a monumental task. It’s so big, in fact, that we’ll never get there by government action alone. No amount of vehicle efficiency standards, forest conservation efforts, or gas taxes can [fully solve the problem](https://www.rff.org/publications/issue-briefs/emissions-projections-for-a-trio-of-federal-climate-policies/). We have to science our way out of it. 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](https://www.bio.org/sites/default/files/2021-04/Climate%20Report%20Executive%20Summary_FINAL.pdf), 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](https://www.eia.gov/environment/emissions/carbon/#:~:text=Energy%E2%80%90related%20CO2%20emissions%20in,economy%20declined%204.9%25%20in%202019.) of the country’s annual CO2 emissions. Take food, for example. Food consumption — and production — is central to human existence. Global food production accounts for [one-quarter of greenhouse gas emissions](https://ourworldindata.org/food-ghg-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](https://science.sciencemag.org/content/370/6517/705) 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](https://unfccc.int/process-and-meetings/the-paris-agreement/the-paris-agreement). 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](https://joynbio.com/). It is 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. Minnesota-based Acceligen is using a technique it calls [precision breeding](https://www.acceligen.com/precision-breeding/) that improves the health of livestock while reducing their waste, greenhouse gas emissions, and water usage. Biotechnology can also help protect food from climate change. As fungal and bacterial infections accelerated by [human-driven environmental disturbances](https://www.nature.com/articles/s41579-019-0222-5) threaten to wipe out Cavendish bananas, [Tropic Biosciences](https://www.tropicbioscience.com/) in the United Kingdom is using CRISPR gene-editing technology to engineer infection-resistant bananas. Companies are also rethinking how food is packaged to reduce plastic pollution and open high-tech paths to broader adoption of biodegradables. This would be a game-changer in the interlinked fight to modulate climate change and protect the oceans. Globally, [100 million tons](https://www.wwf.org.au/news/blogs/plastic-waste-and-climate-change-whats-the-connection#gs.0r1uqu) of plastic are produced every year, [8 million of which ends up in the oceans](https://www.wwf.org.au/news/blogs/plastic-waste-and-climate-change-whats-the-connection#gs.0r1uqu). The production of plastic requires at least 8% of the world’s petroleum. Greenhouse gas emissions from plastic production and incineration [could rise](https://www.wwf.org.au/news/blogs/plastic-waste-and-climate-change-whats-the-connection#gs.0r1uqu) from the current 850 million tons a year to 3 billion tons a year by 2050. And discarded plastic that ends up in the ocean slowly breaks down in sunlight, releasing greenhouse gases and toxic microplastics. Georgia-based [Danimer Scientific](https://danimerscientific.com/) — partnering with the Mars Wrigley candy company — is working on biodegradable packaging that uses plant oils to manufacture “plastic” that dissolves in soil and water. Bioplastics and biopolymers can reduce greenhouse gas emissions reductions by up to [80%](https://www.bio.org/sites/default/files/2021-04/Climate%20Report%20Executive%20Summary_FINAL.pdf) more compared to their petroleum-based counterparts. Fuel is another target for biotechnology. Transportation accounts for the [highest percentage](https://www.epa.gov/ghgemissions/sources-greenhouse-gas-emissions) 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](https://link.springer.com/chapter/10.1007/978-4-431-54895-9_6#:~:text=of%20climate%20change.-,Biofuels%20can%20reduce%20the%20consumption%20of%20fossil%20fuels%20and%20thus,because%20biofuels%20are%20carbon%20neutral.&text=The%20production%20of%20a%20biofuel,material%20for%20making%20liquid%20fuel.) — will be needed to help reduce emissions in transportation and need comparable support. The biotech company [Synthetic Genomics](https://syntheticgenomics.com/algal-cell-factories/#beyond_biofuels), for instance, is utilizing saltwater algae, which 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. Biofuels will also play an important role in air travel. While flying accounts for less than [3% of global CO2 emissions](https://ourworldindata.org/co2-emissions-from-aviation) a year, on a per-mile calculation it’s the least green form of travel. With the number of air travel passengers expected to double by 2040, the Biden administration is upping the financial incentives — through tax credits — for companies that produce sustainable aircraft fuels. Biotech firms are already stepping up. Companies like [Neste](https://www.neste.us/neste-in-north-america), [Gevo](https://gevo.com/), and [World Energy](https://www.worldenergy.net/products/sustainable-aviation-fuel-saf/) are using everything from algae to used or wasted cooking oil to create sustainable jet fuels. [LanzaTech](https://www.lanzatech.com/) recycles carbon from industrial emissions and other sources and turns it into aviation fuel — and has recently [partnered with other corporations](https://techcrunch.com/2020/06/02/lanzajet-launches-to-make-renewable-jet-fuel-a-reality/) 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.

#### Climate Patents and Innovation high now and solving Warming but patent waivers set a dangerous precedent for appropriations - the mere threat is sufficient is enough to kill investment.

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid

The biotech industry is making remarkable advancestowards 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](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), 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](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) 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 compensationand 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. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. 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 proprietaryknow-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 could be devastating to voluntary internationalcollaborations. 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. Necessary Investment Could Diminish 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](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). 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 investat the current and required levels**.**

#### Climate change destroys the world.

Specktor 19 [Brandon; writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years; "Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims," livescience, 6/4/19; <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html>] Justin

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the **sheer complexity of Earth's many interlinked geological processes**; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom. How the world ends What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions. "Thirty-five percent of the global land area, and **55 percent of the global population, are subject to more than 20 days a year of** [**lethal heat conditions**](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), beyond the threshold of human survivability," the authors hypothesized. Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly **one-third of the world's land surface turns to desert**. Entire **ecosystems collapse**, beginning with the **planet's coral reefs**, the **rainforest and the Arctic ice sheets.** The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees. This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to **stress the fabric of the world's largest nations**, including the United States. Armed conflicts over resources, perhaps culminating in **nuclear war, are likely**. The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

## 2

#### Infrastructure is passing now and is at the top of Bidens agenda---Biden has enough PC but continuation is critical.

Nomikos 9/1 [William; 9/1/21; Assistant professor of political science at Washington University in St. Louis and director of the Data-driven Analysis of Peace Project; "*Everyone has an opinion on Afghanistan — Do voters care?*" The Hill, <https://thehill.com/blogs/congress-blog/politics/570422-everyone-has-an-opinion-on-afghanistan-do-voters-care>] Justin

On Aug. 15, Taliban fighters rolled into Kabul, the capital of Afghanistan. They faced little resistance. Within hours, the Taliban had seized control of the city. The airport plunged into chaos as thousands of Afghans sought refuge among departing American personnel. In February 2020, the Trump administration signed a peace agreement calling for the withdraw of American troops, but it is President Biden who ultimately pushed ahead and ended what he called “America’s longest war.” Even now, with the Taliban in Kabul, Biden remains defiant and defends his decision. Democrats worry this will hurt Biden politically, and Republicans are doing their best to make sure it does. But existing research suggests otherwise. Americans don’t prioritize foreign policy when voting International relations scholars long have argued that voters punish presidents who back down from confrontations with foreign adversaries, because doing so could tarnish the U.S.’s reputation abroad. But the magnitude of the effect on presidential approval varies depending on whether Democrats or Republicans are in power, the composition of the president’s constituency, and the persuasiveness of the justification for backing down. Indeed, as my own research has shown, the actual behavior of the president in crises may not matter at all. Ultimately, voters care about whether a president makes the right policy decisions, not whether American forces remain deployed abroad to maintain their reputation. What’s more, Americans are far more likely care about domestic issues such as health care or the economy than foreign policy. For example, even as Barack Obama rode opposition to the war in Iraq to electoral victory in 2008, more than five times as many respondents to the American National Elections Survey (ANES) listed the economy as the most important problem facing the nation compared to the war. Military interventions are unpopular with voters We tend to associate wars with “rally-around-the-flag” effects, in which conflicts lead to popularity bumps for presidents and their parties. Such effects may have been true during WWII, but 21st century military interventions are long, drawn out affairs — and political losers. This is due to what I’ve identified in past research as the time inconsistency between costs and benefits of military interventions. While the costs of intervention accrue immediately, both in terms of actual money as well as human lives, the best-case scenario benefits of intervention take decades, sometimes generations to bear fruit. For politicians facing election campaigns, this means that there is just no incentive to pay the costs of war up front when you might never see the benefits. In research I conducted on troop contributions to the war in Afghanistan, I found that contributors to the war effort — including the United States — withdrew around 10 percent of their forces whenever they were up for reelection. The politics of U.S. casualties Voters do care deeply about the loss of American lives. While images from Kabul evoke memories of Saigon and withdrawal from Vietnam, the more apt comparisons are the capture and failed rescue of U.S. hostages in Teheran following the Iranian revolution in 1979 or the Benghazi embassy attacks in Libya in 2011. Both the Iran hostage crisis and Benghazi negatively affected perception of two presidential candidates, Jimmy Carter and Hillary Clinton, respectively. Biden’s ability to avoid the political fallout might hinge on whether all Americans are evacuated safely. Sadly, this political calculus suggests there may be little room for humanitarian evacuations and refugee resettlements. While Biden has pledged to bring any trapped Americans home, there simply may not be much political incentive to evacuate Afghan refugees – especially if doing so endangers American lives. Moreover, accepting refugees means finding areas in the U.S. willing to resettle them. Conservative media commentators have already seized upon this issue, with one prominent pundit warning his viewers that they will be “invaded” by Afghan refugees. Biden’s political calculation Voters are not closely engaged with current events, often seeking to avoid politics altogether. Humanitarian disasters quickly disappear from headlines. Consider that less than a week after the Taliban overtook Kabul, news from Afghanistan did not make the front page of newspapers is several major cities. On the flip said, the potential costs of staying in Afghanistan would be enormous. Currently, President Biden is focused on getting Congress to pass a $1 trillion infrastructure bill and a $3.5 trillion budget reconciliation bill that, together, would comprise much of his first term agenda. Given the importance of these domestic issues to voters relative to foreign policy, passing the bills through Congress will be the most important politically for Biden. According to estimates, the war in Afghanistan alone has already cost American taxpayers more than $2.2 trillion. Concerns about the combined price tag of Democrats’ legislative agenda have triggered concerns about federal spending and inflation. More spending on Afghanistan would make Biden and his fellow Democrats even more vulnerable to such attacks. The slim margins in Congress suggests that Biden must reserve his political capital to maintain the existing coalitions to pass these two bills, not a new war effort. Doing so would also offer the Democrats the best chance for retaining control of Congress in the 2022 midterm elections.

#### Aff doesn’t solve but requires negotiations that saps PC.

Pooley 21 [James; Former deputy director general of the United Nations’ World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding; “Drawn-Out Negotiations Over Covid IP Will Blow Back on Biden,” Barron’s; 5/26/21; <https://www.barrons.com/articles/drawn-out-negotiations-over-covid-ip-will-blow-back-on-biden-51621973675>] Justin

The Biden administration recently announced its support for a proposal before the World Trade Organization that would suspend the intellectual property protections on Covid-19 vaccines as guaranteed by the landmark TRIPS Agreement, a global trade pact that took effect in 1995.

The decision has sparked furious debate, with supporters arguing that the decision will speed the vaccine rollout in developing countries. The reality, however, is that even if enacted, the IP waiver will have zero short-term impact—but could inflict serious, long-term harm on global economic growth. The myopic nature of the Biden administration’s announcement cannot be overstated.

Even if WTO officials decide to waive IP protections at their June meeting, it’ll simply kickstart months of legal negotiations over precisely which drug formulas and technical know-how are undeserving of IP protections. And it’s unthinkable that the Biden administration, or Congress for that matter, would actually force American companies to hand over their most cutting-edge—and closely guarded—secrets.

As a result, the inevitable foot-dragging will cause enormous resentment in developing countries. And that’s the real threat of the waiver—precisely because it won’t accomplish either of its short-term goals of improving vaccine access and facilitating tech transfers from rich countries to developing ones. It’ll strengthen calls for more extreme, anti-IP measures down the road.

Experts overwhelmingly agree that waiving IP protections alone won’t increase vaccine production. That’s because making a shot is far more complicated than just following a recipe, and two of the most effective vaccines are based on cutting-edge discoveries using messenger RNA.

As Moderna Chief Executive Stephane Bancel said on a recent earnings call, “This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist. And then even if all those things were available, whoever wants to do mRNA vaccines will have to, you know, buy the machine, invent the manufacturing process, invent creation processes and ethical processes, and then they will have to go run a clinical trial, get the data, get the product approved and scale manufacturing. This doesn’t happen in six or 12 or 18 months.”

Anthony Fauci, the president’s chief medical adviser, has echoed that sentiment and emphasized the need for immediate solutions. “Going back and forth, consuming time and lawyers in a legal argument about waivers—that is not the endgame,” he said. “People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible.”

Those claiming the waiver poses an immediate, rather than long-term, threat to IP rights also misunderstand what the waiver will—and won’t—do.

The waiver petition itself is more akin to a statement of principle than an actual legal document. In fact, it’s only a few pages long.

As the Office of the United States Trade Representative has said, “Text-based negotiations at the WTO will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The WTO director-general predicts negotiations will last until early December.

That’s a lot of wasted time and effort. The U.S. Trade Representative would be far better off spending the next six months breaking down real trade barriers and helping export our surplus vaccine doses and vaccine ingredients to countries in need.

#### That solves existential climate change.

Castillo 21 [Rhyma; 8/16/21; News and politics writer at Elite Daily, where she's passionate about advocating for underserved communities throughout the United States. She’s covered issues in politics, immigration, environmental racism, climate change, gun violence, and more. After graduating with an English degree from Texas A&M Unversity, Rhyma has worked as a technical writer and test author at Educational Testing Service (ETS), a copywriter for Mightier Content, and as a Creative Operations Specialist at GoDaddy. She also has bylines as a freelancer at the San Antonio Current, where her reporting on local news, politics, tech, and entertainment has been widely circulated; “*Experts Explain What You Can Do About Climate Change After That Scary IPCC Report*,” Elite Daily, <https://www.elitedaily.com/news/what-you-can-do-climate-change-after-ipcc-report>] Justin

I’ll be honest: climate change is something I have a daily existential crisis over — and with its effects quite literally showing up on people’s doorsteps in the form of floods, wildfires, record heatwaves, and more, I know I’m not alone. On Aug. 9, the Intergovernmental Panel on Climate Change (IPCC) released an alarming report that was characterized as a “code red for humanity,” which is terrifying, to say the least. But while it’s easy to surrender to fatalist feelings of doom and gloom, there’s still time to turn things around. So, according to experts, here’s what you can do about climate change after the IPCC report. While experts agree that reducing, reusing, and recycling on an individual level is important, they acknowledge it isn’t the main solution to climate change, which is a largely institutional problem. According to a 2017 report from the Carbon Disclosure Project (CDP), researchers found that just 100 companies were responsible for over 70% of greenhouse gas emissions since 1988, with the top 10 emitters being fossil-fuel based energy corporations. “I'm not suggesting that individual actions aren't good or important,” states Cara Horowitz, J.D., the co-executive director of the Emmett Institute on Climate Change and the Environment at UCLA School of Law. She adds that if you’re lucky enough to afford an electric vehicle, to select the green option on your energy bill, or to adopt an environmentally sustainable diet, you should absolutely do so. However, she notes that “[climate change] is not a problem that can be solved by individual lifestyle choices.” At least, not in place of widespread social, political, and institutional change. “There is an attempt, and in some ways it's often quite deliberate, to make individuals think it's their fault climate change is happening — if only they made different lifestyle choices, if only they recycled more or ate less meat, we [could] solve this problem,” Horowitz says. But one of the most effective ways to address the climate crisis head-on, she states, is to push for institutional change. Lesley Ott, Ph.D., meteorological researcher at NASA’s Global Modeling and Assimilation Office at Goddard Space Flight Center, agrees. “There’s a limit on how much good or bad any one person can do,” to combat climate change, she states. “This is a situation that’s come from billions of people over decades and decades,” she adds. While she notes that its still important to limit your energy consumption, she acknowledges that large corporations, such as those involved in natural gas, animal agriculture, and product manufacturing, can do a much better job of reducing their emissions. “As climate change is affecting more and more of our infrastructure,” she states, “there are opportunities some companies [could seize] to say ‘hey, you know, I can probably do the right thing for the planet.’” Trained HazMat workers clean up miles oil-drench sand after an off-shore oil spill occurred, Februa... Ott also explains how the climate crisis is both a very difficult and a very simple issue. “It’s simple in that we know what’s causing it,” she says. “We know this is because of greenhouse gases, and we know where the greenhouse gases come from. But it's tricky because those things [that cause greenhouse gases] are so fundamental to many aspects of our lives.” Across the United States and world, many people have no choice but to depend on large energy monopolies for light, gas, and heat. And many people simply cannot afford to purchase electric vehicles, adopt environmentally sustainable diets, or live in neighborhoods where green energy options are available. So, what’s the solution? According to Ott, the answer is clear: “We need to change the way we consume energy,” she states. “We know the path that we need to go down to combat climate change. And it's really up to our political leaders in our country and others to marshal the response, and really put the procedures in place to do just that, to reduce our emissions,” she adds. If it were up to Gavin Schmidt, Ph.D., director of GISS and Principal Investigator for the GISS ModelE Earth System Model at NASA, he’d combat the climate crisis using several strategies: shutting down coal power stations, phasing out natural gas, electrifying transportation systems, investing in infrastructure for more walk-able and bike-able cities, building a more unified power grid, and pushing for improved public transit. But while scientists have developed the technology and resources for these strategies, Schmidt notes many places — including the United States — simply haven’t invested in the infrastructure necessary to adopt these strategies. “The infrastructure is not all there,” he states. So while we certainly have the concepts and resources available, “we're still missing some practical application [for] those things,” he adds. “We have to make the investments, [and] those investments take a while to come to fruition.”

## 3

#### Counterplan text: A nation appointed international panel of scientists including National Academies and corresponding organizations should reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection and manage similar conflicts of interest between intellectual property.

#### International panel of science diplomats can rule over IP---that’s key to science diplomacy.

Hajjar and Greenbaum 18 [David; Dean Emeritus and University Distinguished Professor, and Professor of Biochemistry and Pathology at Weill Cornell Medicine, Cornell University. He is a Fellow of the American Academy of Arts and Sciences, Fellow of the American Association for the Advancement of Sciences, a Jefferson Science Fellow of the National Academies at the U.S. Department of State, and a recent Senior Fellow in Science Policy at the Brookings Institute; Steven; Professor and Chair of the Department of Physics and Astronomy at Hunter College of the City University of New York and a Fellow of the American Physical Society. He was a Jefferson Science Fellow of the National Academies at the U.S. Department of State; “Leveraging Diplomacy for Managing Scientific Challenges,” American Diplomacy; September 18; <https://americandiplomacy.web.unc.edu/2018/09/leveraging-diplomacy-for-managing-scientific-challenges-an-opportunity-to-navigate-the-future-of-science/>] Justin

At the global level, science diplomacy is defined as cooperation among countries in order to solve complex problems through scientific research and education (1). For example, science diplomacy plays an important role in resolving global issues related to the ecosystem (such as clean water, food safety, energy conservation, and preservation of the environment). It also addresses problems related to the healthcare industry. For example, scientists have served at the international level to forge the Middle Eastern Cancer Consortium a decade ago to facilitate better healthcare and improve cancer research in the region. Whether one considers science for diplomacy or diplomacy for science, international science collaborations benefit from allowing science diplomats (broadly defined as science envoys, science attaches, embassy fellows) to help establish positive international relationships between the U.S., Europe, Latin America, Africa or Asia, particularly when proprietary disputes arise (2, 3). These various types of science diplomats already exist; some, like embassy fellows and science envoys, have one-year appointments so their role may be limited, while attaches usually have two or three year appointments that may allow them to be more successful in long, protracted negotiations. In any event, we believe that scientists can play more of a role in advancing international scientific cooperation. A key point addressed here is how to balance security concerns against the need for free exchange of information needed for innovation and growth.

Both the National Science Foundation and the National Institutes of Health are already engaged in supporting American science and strengthening collaborations abroad. Such efforts take advantage of international expertise, facilities, and equipment. Here, we provide a rationale for the use of diplomacy to address scientific challenges. This approach allows some scientists working as diplomats to help manage complex and potentially conflicting situations that arise between scientific communities and their governments. Such issues include managing disputes such as licensing agreements for intellectual property (IP) and providing protection of IP.

International collaborations can not only support but also accelerate the advancement of science. However, collaborations may carry risk if IP is misappropriated for other purposes. International collaborations should have a basis in strategy and specific goals (for example, drug discovery) in order to justify the use of government and/or corporate funds.

About a decade ago, a group of academics from the University of Manchester in the United Kingdom assembled the “Manchester Manifesto,” subtitled “Who Owns Science” (6). This document addressed the lack of alignment between commercial interests, intellectual rights, and credit to the researcher. In our (and commonly held) view, the groups representing these disparate values could benefit from diplomatic mediation. More recently, it has become increasing apparent that managing China as a science and technology superpower represents another challenge for the U.S. Resolution of issues such as ownership of IP, rights to reagents, or use of skilled laboratory personnel from international collaborations may require the efforts of science diplomats. There are few international offices or “guardians” to protect junior and senior scientists in corporate or academic sectors from misuse of reagents or piracy.

China’s failure to respect IP rights, and the resulting piracy, has drawn much attention. The media have also focused on the failure of watchdog government agencies to detect and manage these unwanted activities. Industrial espionage compromises U.S. interests. Moreover, Chinese and Russian hackers have cyberattacked U.S. technology companies, financial institutions, media groups, and defense contractors. In 2018, industrial spying was even reported in a major medical school in New York City where scientists were alleged to have illegally shared research findings with Chinese companies.

The U.S. has a long history of hiring research personnel from other countries to staff its laboratories and industrial R&D centers. These scientists and engineers have made critical contributions to our nation’s well-being and security. These young Chinese and South Asian graduates of U.S. programs a generation ago now staff our research enterprise. However, recent trends in U.S. graduate school applications in science, technology, engineering and mathematics (STEM) reflect a downturn in foreign applicants, particularly from China. It is becoming increasingly apparent that the number of American-born students seeking STEM degrees is not sufficient to satisfy future demands of our high-tech workforce. While our own educational reforms must be augmented, we cannot ignore the need to continue to recruit overseas talent.

We believe that foreign scientists can continue to make critical discoveries in the U. S. provided that their talent is nurtured, developed, and harnessed for the common good. At the same time, American companies cannot hire foreign scientists if they take the ideas they generate in U.S. laboratories back to their home countries without proper credit or permission. If the advancement of science is to succeed, greater diplomatic cooperation is needed to solve and manage proprietary issues for the benefit of all (5, 6).

So, how does one strike the proper balance between security and growth? Science is a universal social enterprise; international conferences lead to friendships and productive collaborations between nations. Given that the U.S. and Chinese governments recognize the need for international communication and collaboration then surely there should be a mechanism for adjudicating anticipated conflicts. One approach would be for government, industrial, and academic stakeholders to form an international panel of scientists and engineers to manage any conflicts of interest between the need to protect proprietary information crucial to a company’s competitive edge, and the need for students and young faculty members to publish their findings. Smaller scale efforts along these lines have recently given rise to unique global partnerships, such as fellowship support by major pharmaceutical companies, which aim to address these conflicts to the benefit of both parties. An added feature of such arrangements is that they often provide corporate financing for research (9). Can this corporate-academic partnership model be adapted to multinational joint R&D efforts while protecting IP? This question falls squarely within the purview of international science diplomacy, whereby science diplomats can establish rules of conduct governing joint global technology development with proper IP protection.

Despite the highly publicized and legitimate piracy allegations against China, at least some data indicates that the Chinese legal system is responding positively to worldwide pressure to honor foreign IP. A 2016 study by Love, Helmers, and Eberhardt, for example, found that between 2006 and 2011, foreign companies brought over 10 percent of patent infringement cases in China, and won over 70 percent of those cases (10). Today, “win rates” average around 80 percent, and “injunction rates,” around 98 percent (10). As Chinese scientists and engineers increasingly enter the top tier of the innovation space, their growing awareness of their own need for IP protection could be a powerful motivating force for the protection of all IP. As stated earlier, science diplomats could catalyze this progress even further by direct negotiations with those parties involved in the conflicts. An obvious flaw in this optimistic outlook is that scientists in the U.S. wield more influence with their government than scientists in China wield with theirs. And to the extent that the Chinese government could be encouraging IP theft, this must be addressed first by those international companies/firms who want to do business with the Chinese. Chinese investments, as well as tech incubators and targeted acquisitions, can enable access to U.S. technologies for commercial development. Although this conveys a level of risk to the developers, it may provide valuable opportunities for U.S. companies as well. In many respects, the extensive engagement and collaboration in innovation between the U.S. and China, often characterized by open exchanges of ideas, talent, and technologies, can be mutually beneficial in enriching and accelerating innovation in both countries.

In summary, we believe that science diplomats could help address the increasingly complex issues that arise between accelerating scientific and engineering advances, and the need to protect national security and corporate IP. We also propose that this might be accomplished by asking the National Academies to **recommend** academic, corporate, and government scientific leaders to serve on an international scientific advisory board, and for the corresponding organizations in other countries to do the same. Access to the free flow of information promotes new knowledge and innovation. A return to a more restrictive intellectual environment is not only harmful to progress, but also nearly impossible to manage in the current internet age. A good place to start would be to engage the newly appointed head of the White House Office of Science and Technology Policy (the Science Advisor to the President of the United States), and working groups within established organizations. These organizations include the American Association for the Advancement of Science (AAAS) or the National Academies of Science, Engineering and Medicine, and corresponding international organizations. What incentive is there for a busy and successful scientist to serve in such capacity? It is the same altruism that motivates us to accept assignments as journal editors, manuscript reviewers, or funding agency panelists for the advancement of science toward the greater good.

#### Solves every existential threat.

Haynes 18—research associate in the Neurobiology Department at Harvard Medical School (Trevor, “Science Diplomacy: Collaboration in a rapidly changing world,” <http://sitn.hms.harvard.edu/flash/2018/science-diplomacy-collaboration-rapidly-changing-world/>, dml) // Re-Cut Justin

Today’s world is extremely interconnected. Most of us take this fact for granted, but its implications cannot be overstated. The rate at which information, resources, and people are able to move from one part of the world to another continues to accelerate at an alarming rate. Undoubtedly, this development has done society immense good. In the last century, global life expectancy has doubled, the percentage of people living in extreme poverty has dropped by about 60%, and world literacy rates have increased by a similar margin. But while these statistics paint a promising picture of human civilization, human progress rests on a fragile foundation of international cooperation; the challenges presented by an interconnected world are immense. War, natural disasters, and economic collapse now exert their effects globally, creating economic and ecological disasters and mass human migrations on an unprecedented scale. And with the US pulling out of major multilateral agreements on trade, climate change mitigation, and denuclearization, you might wonder if our ability to collaborate across borders productively is really up to the task.

Global challenges require global solutions, and global solutions require collaboration between countries both big and small, rich and poor, authoritative and democratic. There are few human enterprises capable of providing continuity across these differences, and as technological solutions are becoming available to some of our most pressing issues, two in particular will be necessary to getting the job done: science and diplomacy. While science has long been utilized as a means to reach political ends—think of British explorer James Cook’s mapping of unexplored continents or the United States’ Manhattan Project—a more formal integration of scientists into the diplomatic process is being undertaken. This effort, which has led to scientists and academics playing a direct role in foreign policy development and international relations, has given birth of a new branch of diplomacy: science diplomacy.

What is science diplomacy?

As both the term and concept of science diplomacy have only recently gained traction in scientific and diplomatic circles, it’s been given a variety of definitions. But common to them all is the focus on applying scientific expertise to an international effort. The focus of these efforts is to solve international problems collaboratively while balancing economic prosperity, environmental protection, and societal wellbeing. The challenge of reaching this balance in the face of a booming global population cannot be understated, but this new branch of diplomacy is already at work and is producing results. International agreements such as the Paris Climate Agreement and the Iran Nuclear Deal are two famous examples, and science diplomacy is also establishing international collaboration in many other important arenas. While these lesser known efforts may not dominate the headlines, they are quietly tackling the global issues of today and preparing us for those of tomorrow.

Natural disasters don’t respect national boundaries (and neither does the aftermath)

In 2013, the number of refugees displaced by natural disasters—hurricanes, droughts, earthquakes—outnumbered those displaced by war. Current projections estimate as many as 1 billion people may be displaced by natural disasters by the year 2050. That would mean 1 in 9 people on the planet displaced and looking for a home. Compare this to the estimated 12 million refugees displaced by the war in Syria, and a frightening picture begins to form. As natural disasters continue to increase in both their frequency and intensity, solutions for mitigating the risk of total catastrophe will be underpinned by science, technology, and the ability of the international community to collaborate. Many organizations are starting to tackle these problems through the use of science diplomacy. The center for Integrated Research on Disaster Risk (IRDR) is composed of ten national committees—a network of government sponsored research institutions across the world in countries ranging the political and economic scale. These working groups have committed to improving disaster-risk-reduction science and technology while providing guidance to policy makers charged with implementing disaster prevention and mitigation strategies.

IRDR is governed by a committee comprising experienced scientists and natural disaster experts. Its members come from all over the world—the US, China, Uganda, Norway, Mexico, Venezuela, and more. The diversity of this organization starts at the top and is crucial to developing comprehensive risk-reduction strategies. Data and insights from countries with varying areas of expertise are being shared and built upon, facilitating more accurate natural disaster forecasting and better strategies for mitigating their destructive power. And by including representatives from countries of varying political and economic power in its leadership, IRDR ensures that its work will consider the needs of the global community at large, rather than just nations with considerable wealth and political standing.

The results of this type of international collaboration speak for themselves. Although humanity is grappling with more natural disasters than ever before, deaths related to these incidents continue to trend downward. Operating outside of the typical political framework that dominates foreign relations, IRDR provides a model for effective collaboration across the geopolitical spectrum in the face of a major global issue.

Explore or Exploit? Managing international spaces

Over the last few decades the polar ice cap that covers much of the Arctic Ocean has been shrinking. So much so, that during the warm season vast areas of previously solid ice have become open waters, creating opportunities for new trade routes and exposing the Arctic’s enormous reserves of oil and natural gas. Depending on your values, this will sound either like an opportunity for huge economic development of the region or the inevitable exploitation of one of the last untouched natural territories on the planet. And if you live there, like the half a million indigenous people who currently do, how this territory is managed will determine where you can live, how (and if) you can make a living, and what the health of the ecosystems that have supported Arctic life for millennia will look like.

Luckily, such a scenario was predicted decades ago. In 1987, Mikhail Gorbachev, then leader of the then Soviet Union, delivered a speech outlining his aspirations for the arctic to be explored rather than exploited—to radically reduce military presence, create a collaborative multinational research effort, cooperate on matters of environmental security, and open up the Northern Sea Route for trade. This speech laid the foundation for the Arctic Council (Figure 1), which is one of the most successful examples of science diplomacy at work. Composed of the eight Arctic nations, including geopolitical rivals US and Russia, and numerous groups of indigenous peoples, the Arctic Council was established to maintain Gorbachev’s vision for the region while giving the indigenous peoples a seat at the negotiating table. The council’s activities are conducted by six scientific and technology-based working groups who conduct research in the area and provide knowledge and recommendations to the council members. As a result of this research, and allowing scientists to take part in the negotiations, the Arctic council has enacted several legally binding agreements regarding the sustainable development and environmental protection of the Arctic Ocean. These agreements have facilitated cooperation on a number of important issues including search and rescue operations, prevention and containment of maritime oil pollution, and, most recently, enhanced data sharing and scientific research collaborations. Against a backdrop of rapidly deteriorating diplomatic relations, the US and Russia have co-chaired task forces that laid the foundation for these agreements, proving to the world that meaningful results can be achieved through the avenue of science diplomacy, regardless of geopolitics.

Science diplomacy going forward

The technical expertise that characterizes science diplomacy will continue to be in demand across many realms of foreign policy. For example, synthetic biology and gene-editing technology continue to factor into matters regarding agriculture and trade. Also, digital currencies, such as bitcoin, have changed the way economists and businesses are approaching markets. Finally, machine learning and artificial intelligence are being used by governments as a means for population control, giving rise to a new type of governance—digital authoritarianism.

While this expertise will be necessary for managing such issues, building international coalitions can’t be done through a purely scientific and technical lens. Convincing others to cooperate means providing them with a convincing argument to do so, and in terms they understand and find compelling. To achieve this, scientists must be trained to communicate their expertise in a way that moves stakeholders in policy discussions to act. This means appealing to motivations they have been largely taught to put to the side—whether they be political, economic, or emotional in nature—without obscuring the data and insights they have to offer.

For our leaders, policy makers, and diplomats to effectively understand issues underpinned by science and technology, experts in these fields must continue to be integrated into the mechanisms of governance. With scientists in the US running for elections in numbers like never before, we can expect this trend to continue. And in the face of a rising wave of nationalism across the world, it is crucial that we do everything we can to foster collaboration. The future of human civilization depends on it.

## 4

#### CP text: The member nations of the World Trade Organization should add more stringent requirements for filing secondary patents by requiring secondary patent filers to demonstrate increased efficacy as compared to the original. Solves all your offense by reducing purely strategic patents while permitting R and D for

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions

(a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.

(b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5

(c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06

Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected.

Lowell provides some precedent for creating a higher utility standard. 07 This new standard would focus on a drug's overall improved efficacy, rather than a minor tweak in the formula that would mitigate or resolve a previously caused side effect. This standard would require holding the pharmaceutical industry to a higher standard than other industries, which could potentially conflict with the United States' TRIPS Agreement obligations with the WTO.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace.

1. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6
2. A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

## Case

### 1NC – AT: Evergreening

#### Evergreening is a myth – this card ends the debate.

Lietzan 20 [Erika; Professor of Law, University of Missouri School of Law, Research interests in Pharmaceutical Regulation, Device Regulation, Intellectual Property; “The Evergreening Myth Claims that drug innovators extend their patents obscure a radical policy‐​making goal.,” Cato Institute; Fall 2020; <https://www.cato.org/regulation/fall-2020/evergreening-myth>/] Justin

In recent years, U.S. policymakers have considered proposals intended to prevent — or at least reduce — “evergreening” by pharmaceutical companies. Some proposals would change the antitrust enforcement landscape, others the intellectual property landscape, and still others the regulatory framework that governs new medicines. Some proposals — such as those creating new causes of action under the antitrust laws or limiting the availability of patents for discoveries — are profound and their proponents cite a body of academic and policy literature that decries supposed “evergreening” by companies to justify their ideas.

The term “evergreening” is a metaphor, meant to remind audiences of evergreen trees, which have green foliage year‐​round. It implies that something has been extended, and users of the metaphor view this extension as improper or undesirable. When offering descriptions and examples of evergreening, they focus on drug companies continuing to innovate after first introducing a new molecule, and on the broader marketplace for medicines after subsequent innovations have been introduced to the market. But proponents are frustratingly inconsistent and unclear about what, exactly, has been “extended” in these situations. A close look at the regulatory landscape in which continuing pharmaceutical innovation occurs shows that arguments for reform are grounded in myths, such as the myth that pharmaceutical companies continuing to innovate somehow “extend” their patents.

Once the myths of “evergreening” are laid bare, it becomes apparent that proponents of these proposals really want for the government to limit medical innovators to one medical product in the marketplace for each useful new molecule discovered. They are arguing that an innovator should not enjoy an exclusive market — and the resulting advantageous pricing — for innovations that, though discrete and independently satisfying the standard for a patent under U.S. law, stem in some fashion from an earlier innovation for which that innovator separately enjoyed exclusivity and the resulting pricing advantages. Or, at least, that drug innovators should not. This is a radical proposal that merits careful reflection and discussion, and it is not ripe for action. Understanding that this is the true policymaking objective requires unpacking the regulatory landscape and market more carefully, and paying closer attention to word choice, than proponents of reform often do. The Evergreening Allegation In the United States, every new medicinal product requires premarket approval from the Food and Drug Administration. The drug statute refers to approval of a “new drug,” and ambiguity in the term “drug” provides fertile ground for confusion and rhetorical mischief, as discussed later in this article. A firm that wants to market a new drug must prove to the FDA that the drug is safe and effective. Generating this information takes years, beginning with work in the laboratory and on animals, and progressing through several rounds of “clinical” testing in humans. For new molecules, the clinical portion of this research and development program averages six years. The process is also expensive: the Tufts Center for the Study of Drug Development now estimates the average cost of developing a new molecular entity at $2.6 billion. That figure includes average out‐​of‐​pocket costs of $1.4 billion and reflects the cost of unsuccessful projects. Most research and development programs fail. When new drugs are first launched by innovators, they tend to be sold under brand names and protected by patents as well as statutory rights in the data that supported FDA approval (known as “data exclusivity”). Although the pricing of these products may reflect competitive pressure from other branded products, it also reflects the fact that patent rights and statutory data exclusivity delay the launch of cheaper copies. But no more than five years later, and often earlier, the innovator’s competitors may file applications seeking approval of their own products based on the innovator’s research, rather than performing their own. They file what are known as “abbreviated applications” — abbreviated because they omit some, or all, of the research needed to prove safety and effectiveness. Abbreviated applications are much less expensive and time‐​consuming to assemble, and the competitors’ drugs correspondingly much less expensive than the original drugs they copy. When a competitor seeks to market an exact copy through an abbreviated application, we call its drug a “generic” drug. Pharmacists usually dispense generic copies even when doctors prescribe the corresponding branded products by name. Some people use the “evergreening” label when an innovator holds more than one patent protecting its product, especially if some patents expire later than others. More often, though, these people use the label when an innovator introduces a newer version of its own product that is already on the market. These newer products tend to be sold under brand names and protected by their own patents and statutory data exclusivity. Sometimes the innovator also stops selling its older product. If purchasers shift to the innovator’s newer product rather than purchasing cheap copies of the innovator’s older product, some say the innovator has engaged in evergreening. Although the term “evergreening” is a metaphor and signifies an extension of something, proponents of reform proposals do not agree on the particulars of the term’s use. Some say the company has evergreened its invention, its drug, or its product. Others say the company has evergreened the drug’s patent or patent life, or its exclusivity. Some say it has extended the drug’s patents, or the drug’s patent coverage or patent life, or the drug’s exclusivity period. Some say the company has evergreened the drug’s price, or its own profits or monopoly, or the company has extended its market power. Many argue that through evergreening — whatever the term means — the innovator has improperly blocked other firms from competing with it. On this basis, they seek government intervention. For instance, one recent proposal would allow the Federal Trade Commission to bring antitrust actions against innovators who introduced newer products to replace their older products. Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows.

Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date.

There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention.

Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked.

First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process.

If a competitor wants to offer a different route of administration, dosage form, or strength — for instance, to avoid infringing a patent — it may still be able to use the generic drug approval pathway. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses.

Second, an abbreviated application cites a specific innovative product, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that specific product alone. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.)

To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation.

Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of only the patents associated with the specific product that it references. The competitor does not have to contend with patents associated with other products that happen to contain the same active ingredient or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity.

This debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products can prevent its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could seek a license. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also other options.

Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A competitor may be able to design around patents claiming other aspects of the innovator’s product (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents.

It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient.

Myth that automatic substitution is critical / The final myth of evergreening is that continuing innovation — especially when an innovator introduces a newer version of its product and stops selling its old version — precludes uptake of less expensive medicines by interfering with automatic pharmacy substitution under state pharmacy law. This myth reflects an assumption that competitors who file abbreviated applications depend on automatic pharmacy substitution — rather than the ordinary rough and tumble of a competitive marketplace — to obtain market share. The truth may be more complicated.

Automatic pharmacy substitution arises through a combination of longstanding FDA practices and state pharmacy law. Once the agency has approved two products with the same active ingredient, it assesses whether they are “therapeutically equivalent.” Designating two as therapeutically equivalent means that they have the same clinical profile and that they can be “substituted”: either can be dispensed instead of the other. A true generic drug, an exact copy of the innovator’s product approved based on an ANDA, will be deemed therapeutically equivalent. Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to. The notion advanced by critics of alleged “evergreening” is that once an innovator introduces a newer version of its branded product, doctors will prescribe the newer version. And because the generic company instead copied the older version, pharmacists will not — cannot under state law — substitute the generic product when the patient presents a prescription for the newer innovator product.

The problem with this argument is that actual dispensing decisions probably reflect a more complex interaction of prescriber decisions, payer preferences, and state law. To begin with, a doctor may specify either branded drugs or generic drugs. A doctor could write the brand name, to be sure, but the doctor could also simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs. In theory, the doctor could even identify a particular generic company’s drug containing a particular active ingredient. And while drugmakers rarely promote generic drugs to doctors and patients, nothing prevents them from doing so. They do promote their therapeutically equivalent generic drugs to pharmacies and payers, focusing on the lower prices they offer. And a company that filed a hybrid application for a product that differed from the innovator’s product might brand its product and promote the distinguishing features, or (depending on the reason it filed the hybrid application) position the product as a near‐​duplicate of the more expensive branded alternatives and promote it as such.

In short, an innovator’s newer product creates a new choice for doctors and payers. To be sure, if doctors select this product, pharmacists will dispense it rather than generic copies of the innovator’s older product. Doctors might shift their prescribing to the newer product for many reasons, including persuasive advertising and promotion — meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product. They might shift for other reasons, including experience treating patients with the two options. But companies may advertise and promote generic products to doctors and patients as well, and based on this advertising (or for other reasons, such as experience with the older innovative product that the competitor copied) doctors might not select the innovator’s newer product. They might specify the innovator’s older product (which would lead to automatic substitution, even if the innovator no longer markets the product) or, again, a generic product itself.

Generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market.

The assumption that competing companies depend on automatic substitution for market share may be simplistic. Only a minority of states require substitution; most instead have permissive laws. In these states, if a generic product is therapeutically equivalent to the prescribed product and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient’s insurance, without consulting the physician. In these cases, the patient’s insurance drives the product selection. State law just makes it possible to comply with the insurance without contacting the doctor. If a payer perceives the innovator’s new product as less cost effective than available generic drugs containing the same active ingredient, it may decline to cover the product. A rational payer will adopt strategies that steer doctors and patients to less expensive products that are equally or adequately effective — not only those that are therapeutically equivalent, but also those that are not. In these cases, even if a doctor specifies a branded product, the patient’s insurance might prompt a conversation among the doctor, pharmacist, and patient, ultimately leading to modification of the prescription and dispensing of the cheaper copy of the innovator’s first‐​version product.

In short, when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. In this scenario, products compete for the business of rational payers based on their comparative benefits and cost. Substitution may play almost no true role, and whether the innovator still markets its older branded product may be irrelevant.

#### Prefer legal studies.

Parker and Mooney 7 [Scott and Kevin; “Is ‘evergreening’ a cause for concern? A legal perspective,” Journal of Commercial Biotechnology; 2007; <https://link.springer.com/article/10.1057/palgrave.jcb.3050066>] Justin

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.