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#### Biotech R&D is set for high growth and investment now

NASDAQ 8/9 [NASDAQ is a stock market index that includes almost all stocks listed on the Nasdaq stock exchange. Along with the Dow Jones Industrial Average and S&P 500, it is one of the three most-followed stock market indices in the United States. This article was written by NASDAQ contributors and published on CNBC. The editorial staff of CNBC did not contribute to the creation of this study.) “Why the Nasdaq Biotechnology Index is poised for a run of sustainable growth” CNBC, NASDAQ, 8/9/2021, <https://www.cnbc.com/advertorial/2021/08/09/why-the-nasdaq-biotechnology-index-is-poised-for-a-run-of-sustainable-growth-.html>] RM

Between the recent bio innovation success stories in the battle against Covid-19 and the technology-driven advances ushering in new efficiencies for research and development (R&D), **the biotech industry has never been more relevant**.

As home to more than 265 companies, the pioneering Nasdaq Biotechnology Index (NBI) has long been committed to providing healthcare’s innovators with access to the capital they need to keep moving forward. Now, investors have access to the Index’s companies through a new ETF, the Invesco Nasdaq Biotechnology ETF (IBBQ).

Launched in 1993, in the wake of the original “biotech revolution” led by the discovery of recombinant DNA, NBI® remains the most representative index in the space. In fact, 98% of all U.S. listed biotech companies are listed on Nasdaq. When considering the massive growth taking place in the sector, it’s no surprise that NBI has outperformed both the S&P 500 (SPX) and Health Care Select Sector Index (IXVTR) in certain market environments.

According to Mark Marex, Index R&D Senior Specialist for Nasdaq who recently compiled an in-depth report on the NBI, global events and digital acceleration have contributed to the Index’s recent strong performance; and Nasdaq’s dedication to maintaining a true benchmark for technology-driven healthcare innovation has provided a framework for growth.

Building the ideal benchmark

Given the existence of pureplay biotech firms, hybrid biopharmaceutical companies, and less R&D-intensive pharmaceutical manufacturers, creating a single benchmark that truly captures the biotech sector and the symbiotic relationships among its players is no easy task.

One of the unique aspects of NBI, versus biotech-focused indexes created by other index providers, is its subsector classifications split between Biotechnology and Pharmaceuticals. As of June 30, 2021, ICB (FTSE Russell’s Industry Classification Benchmark) classified 222 NBI companies as Biotechnology and 47 as Pharmaceuticals. The resulting split by index weight is approximately 65% and 35%, respectively, which illustrates the major difference between the two groups: Pharmaceutical companies tend to be much larger than Biotechnology firms.

This split within a single index provides advantages for investors: While offering some exposure to more established pharmaceutical companies, it also includes R&D-heavy biotech firms that over time may transition into biotech-driven pharma companies. That’s exactly what happened this year when NBI’s largest company, Amgen (AMGN / $144Bn), was reclassified by ICB from Biotechnology to Pharmaceuticals. By retaining firms as they straddle the two classifications over the course of their lifecycle, NBI presents potential growth advantages when compared with index providers that focus rigidly on one classification versus the other.

Home to world-changing breakthroughs

Nasdaq’s vision for the Index has served it well, **both in terms of its longevity and its current role as a champion of the companies paving the way for a post-pandemic world through their technological advances and life-saving treatments**. The broad reach of NBI constituents across multiple fronts in the fight against Covid-19, for example — from diagnosis to vaccines and treatment —demonstrates the strength of its core approach.

NBI companies including Gilead and Regeneron made headlines for their successes during the pandemic with antiviral therapeutics and antibody-based therapeutics for high-risk patients. But it’s the stunning success of m-RNA vaccine technology from Moderna and BioNTech, two NBI companies, that most clearly showcase the home run potential among the biotech entrepreneurs in the space.

And while NBI is currently up 8.2% YTD on a price-return basis (as of June 30) **versus a broader market gain of 14.4% by SPX**, the S&P Biotechnology Select Industry Index (SPSIBI) is down 3.7%.

It’s worth noting that in 2020, NBI outperformed SPX with a price gain of 25.7% versus 16.3%, respectively. This shows the resilience of the NBI and the inherent strength of its current mix of companies.

The possibilities of accelerated R&D

As a whole, the life-changing work being done by NBI constituents requires enormous amounts of R&D. In 2020, R&D expenses for the entire group totaled $68.5Bn, nearly 31% of these companies’ revenue totals. Two-thirds of NBI’s firms reported R&D expenses that exceeded their revenues

For several NBI companies, however, these massive investments provided tangible benefits in the fight against Covid-19. Undoubtedly, years of back-end work and minimal profits ultimately helped deliver the very products that are now driving historic returns. Psychologically, their breakthroughs demonstrated the enormous potential of science and technology to serve humankind.

Looking ahead, **revolutions in Mapping and Engineering processes, boosted by rapid advancements in Machine Learning and Artificial Intelligence, are fostering a true fusion of Biology and Technology that could transform the traditionally costly and labor-intensive R&D function**. Some research estimates these advances could reduce the failure rate of drugs by up to 45% and shorten drug trials by up to 50%. The result could be even more breakthroughs, performed much more efficiently, greatly increasing the returns on biopharmaceutical R&D.

Even a conservative interpretation of the above numbers would significantly reduce R&D costs and boost the market capitalization of therapeutics companies from the current $2Tn up to $9Tn as soon as 2024, according to estimates from ARK Financial.

Meanwhile, increasingly cost-effective human genomics could revolutionize several other industries, from agriculture to biofuels.

By any measure, there is much to be excited about across the spectrum of biotech — especially coming out of a global pandemic. And while no person, nor index, can truly predict what the future holds, chances are strong that companies sitting within NBI will have a hand in leading the way.

“**For investors**, the Index already serves as a fascinating lens through which to view human society’s scientific and technological advancements,” says Mark Marex. “To me, it’s very exciting to ponder what the researchers, scientists, and business leaders in this space will accomplish next.”

#### IPR protections are key to sustain healthcare investments and manufacturing. Independently, it’s key to broader vaccine production.

Roberts 6/25/21 [James M. Roberts is a Research Fellow for Economic Freedom and Growth at the Heritage Foundation. Roberts' primary responsibility as one of The Heritage Foundation's lead experts in economic freedom and growth is to edit the Rule of Law and Monetary Freedom sections of [Index of Economic Freedom](https://www.heritage.org/index/). An influential annual analysis of the economic climate of countries throughout the world, the Index is co-published by Heritage and The Wall Street Journal.) “Biden’s OK of Global Theft of America’s Intellectual Property is Wrong, Dangerous.” 6/25/2021, The Heritage Foundation, Commentary—Public Health] RM

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.

**Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes**.

The best way to prevent and treat new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

Three U.S. companies—Pfizer, Moderna, and Johnson & Johnson—created and manufactured the world’s most effective mRNA COVID vaccines in record time. An increasing majority of Americans have now been inoculated, but much of the developing world remains in desperate need of vaccines. Americans naturally want to help. The question is how.

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines. This, he said, would help make the vaccines more plentiful and available in needy countries. **It’s a short-sighted approach and doomed to fail.**

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them.

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. **It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.**

Signaling that the United States will not fight to defend their intellectual property rights **actively undermines innovation and manufacturing** in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the **future development of vaccines** needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, **compulsory licensing legalizes the theft of intellectual property**. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding.  **It is and has been a bulwark of American prosperity**, but the strength of that protection has been weakening in the past few decades. **Compulsory licensing contributes to the erosion** of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

**The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production**.

That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### COVID was a precursor to deadlier pandemics—vaccine production will determine everything.

Lander 8/4/21 [Eric Lander, President Biden’s Science Advisory and Director of the White House Office of Science and Technology Policy) “Opinion: As bad as Covid-19 has been, a future pandemic could be even worse—unless we act now” 8/4/21, The Washington Post] RM

[Coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_3) vaccines can end the current pandemic if enough people choose to protect themselves and their loved ones by getting vaccinated. But in the years to come, we will still need to defend against a pandemic side effect: collective amnesia.

As public health emergencies recede, societies often quickly forget their experiences — and **fail to prepare for future challenges**. For pandemics, such a course would be disastrous.

**New infectious diseases have been emerging at an accelerating pace,** and they are spreading faster.

Our federal government is responsible for defending the United States against future threats. That’s why President Biden has asked Congress to fund his plan to build on current scientific progress to keep new infectious-disease threats from turning into pandemics like covid-19.

As the president’s science adviser, I know what’s becoming possible. For the first time in our history, we have an opportunity not just to refill our stockpiles but also to transform our capabilities. However, **if we don’t start preparing now for future pandemics, the window for action will close.**

Covid-19 has been a catastrophe: The toll in the United States alone is [more than 614,000 lives](https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/?itid=lk_inline_manual_11) and has been estimated to exceed [$16 trillion](https://jamanetwork.com/journals/jama/fullarticle/2771764), with disproportionate impact on vulnerable and marginalized communities.

But a future pandemic could be even worse — unless we take steps now.

It’s important to remember that the virus behind covid-19 is far less deadly than the 1918 influenza. The virus also belongs to a well-understood family, coronaviruses. It was possible to design vaccines within days of knowing the virus’s genetic code because 20 years of [basic scientific research](https://science.sciencemag.org/content/372/6538/109.full) had revealed which protein to target and how to stabilize it. And while the current virus spins off variants, its mutation rate is slower than that of most viruses.

**Unfortunately, most of the 26 families of viruses that infect humans are less well understood or harder to control**. We have a great deal of work still ahead.

The development of [mRNA vaccine technology](https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/?itid=lk_inline_manual_17) — thanks to more than a decade of foresighted basic research — was a game-changer. It shortened the time needed to design and test vaccines to less than a year — far faster than for any previous vaccine. And it’s been surprisingly effective against covid-19.

Still, there’s much more to do. We don’t yet know how mRNA vaccines will perform against other viruses down the road. And **when the next pandemic breaks out, we’ll want to be able to respond even faster.**

Fortunately, the scientific community has been developing a bold plan to keep future viruses from becoming pandemics.

Here are a few of the goals we should shoot for:

The capability to design, test and approve safe and effective vaccines within 100 days of detecting a pandemic threat (for covid-19, that would have meant May 2020); manufacture enough doses to supply the world within 200 days; and speed vaccination campaigns by replacing sterile injections with skin patches.

Diagnostics simple and cheap enough for daily home testing to limit spread and target medical care.

Early-warning systems to spot new biological threats anywhere in the world soon after they emerge and monitor them thereafter.

We desperately need to strengthen our public health system — from expanding the workforce to modernizing labs and data systems — including to ensure that vulnerable populations are protected.

And we need to coordinate actions with our international partners, because pandemics know no borders.

These goals are ambitious, but they’re feasible — provided the work is managed with the seriousness, focus and accountability of NASA’s Apollo Program, which sent humans to the moon.

Importantly, these capabilities won’t just prepare us for future pandemics; they’ll also improve public health and medical care for infectious diseases today.

Preparing for threats is a core national responsibility. That’s why our government invests heavily in missile defense and counterterrorism. We need to similarly protect the nation against biological threats, which range from the ongoing risk of pandemics to the possibility of deliberate use of bioweapons.

Pandemics cause massive death and disruption. From a financial standpoint, they’re also astronomically expensive. If, as might be expected from [history](https://www.cfr.org/timeline/major-epidemics-modern-era) and current trends, we suffered a pandemic of the current scale every two decades, the annualized cost would exceed $500 billion per year. Investing a much smaller amount to avert this toll is an economic and moral imperative.

The White House will put forward a detailed plan this month to ensure that the United States can fully prepare before the next outbreak. It’s hard to imagine a higher economic or human return on national investment.

#### Ecosystem sensitivity from climate change means future pandemics will cause extinction—assumes COVID

Supriya 4/19 [Lakshmi Supriya got her BSc in Industrial Chemistry from IIT Kharagpur (India) and a Ph.D. in Polymer Science and Engineering from Virginia Tech (USA). She has more than a decade of global industry experience working in the USA, Europe, and India. After her Ph.D., she worked as part of the R&D group in diverse industries starting with semiconductor packaging at Intel, Arizona, where she developed a new elastomeric thermal solution, which has now been commercialized and is used in the core i3 and i5 processors. From there she went on to work at two startups, one managing the microfluidics chip manufacturing lab at a biotechnology company and the other developing polymer formulations for oil extraction from oil sands. She also worked at Saint Gobain North America, developing various material solutions for photovoltaics and processing techniques and new applications for fluoropolymers. Most recently, she managed the Indian R&D team of Enthone (now part of MacDermid) developing electroplating technologies for precious metals.) “Humans versus viruses - Can we avoid extinction in near future?” News Medical Life Sciences, 4/19/21, https://www.news-medical.net/news/20210419/Humans-versus-viruses-Can-we-avoid-extinction-in-near-future.aspx] RM

Expert argues that human-caused changes to the environment can lead to the emergence of pathogens, not only from outside but also from our own microbiome, which can pave the way for large-scale destruction of humans and **even our extinction**.

Whenever there is a change in any system, it will cause other changes to reach a balance or equilibrium, generally at a point different from the original balance. Although this principle was originally posited by the French chemist Henry Le Chatelier for chemical reactions, this theory can be applied to almost anything else.

In an essay published on the online server Preprints\*, Eleftherios P. Diamandis of the University of Toronto and the Mount Sinai Hospital, Toronto, argues that changes caused by humans, to the climate, and everything around us will lead to changes that may have a dramatic impact on human life. Because our ecosystems are so complex, we don’t know how our actions will affect us in the long run, so humans generally disregard them.

Changing our environment

Everything around us is changing, from living organisms to the climate, water, and soil. Some estimates say about half the organisms that existed 50 years ago have already become extinct, and about 80% of the species may become extinct in the future.

As the debate on global warming continues, according to data, the last six years have been the warmest on record. Global warming is melting ice, and sea levels have been increasing. The changing climate is causing more and more wildfires, which are leading to other related damage. At the same time, increased flooding is causing large-scale devastation.

One question that arises is how much environmental damage have humans already done? A recent study compared the natural biomass on Earth to the mass produced by humans and found humans produce a mass equal to their weight every week. This human-made mass is mainly for buildings, roads, and plastic products.

In the early 1900s, human-made mass was about 3% of the global biomass. Today both are about equal. Projections say by 2040, the human-made mass will be triple that of Earth’s biomass. But, slowing down human activity that causes such production may be difficult, given it is considered part of our growth as a civilization.

Emerging pathogens

Although we are made up of human cells, we have almost ten times that of bacteria just in our guts and more on our skin. These microbes not only affect locally but also affect the entire body. There is a balance between the good and bad bacteria, and any change in the environment may cause this balance to shift, especially on the skin, the consequences of which are unknown.

Although most bacteria on and inside of us are harmless, gut bacteria can also have viruses. If viruses don’t kill the bacteria immediately, they can incorporate into the bacterial genome and stay latent for a long time until reactivation by environmental factors, when they can become pathogenic. They can also escape from the gut and enter other organs or the bloodstream. Bacteria can then use these viruses to kill other bacteria or help them evolve to more virulent strains.

An example of the evolution of pathogens is the cause of the current pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several mutations are now known that make the virus more infectious and resistant to immune responses, and strengthening its to enter cells via surface receptors.

The brain

There is evidence that the SARS-CoV-2 can also affect the brain. The virus may enter the brain via the olfactory tract or through the angiotensin-converting enzyme 2 (ACE2) pathway. Viruses can also affect our senses, such as a loss of smell and taste, and there could be other so far unkown neurological effects. The loss of smell seen in COVID-19 could be a new viral syndrome specific to this disease.

Many books and movies have described pandemics caused by pathogens that wipe out large populations and cause severe diseases. In the essay, the author provides a hypothetical scenario where a gut bacteria suddenly starts producing viral proteins. Some virions spread through the body and get transmitted through the human population. After a few months, the virus started causing blindness, and within a year, large populations lost their vision.

Pandemics can cause other diseases that can threaten humanity’s entire existence. **The COVID-19 pandemic brought this possibility to the forefront**. If we continue disturbing the equilibrium between us and the environment, we don’t know what the consequences may be and **the next pandemic could lead us to extinction.**

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### Extinction

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

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#### States except the United States should reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection.

#### The United States Federal Judiciary should rule that not reducing intellectual property protections for medicines by implementing a one-and-done approach for patent protection is unconstitutional.

#### Solves and they can do it – empirical influence over medicine

Capone 20 [Connie Capone, writer for MDLinx, September 3, 2020. “Court rulings that changed medicine” [https://www.mdlinx.com/article/court-rulings-that-changed-medicine/147FEf8WGxGdBQI4b8HG7u Accessed 8/27](https://www.mdlinx.com/article/court-rulings-that-changed-medicine/147FEf8WGxGdBQI4b8HG7u%20Accessed%208/27) //gord0]

What happens when technology firms, insurance companies, healthcare systems, and even the US government encroach on medical practice? In short, the courts get involved. Court decisions have frequently ruled on medical ethics and shaped healthcare policy. Landmark Supreme Court cases and lower court rulings have set the tone on medical ethics and shaped healthcare policy. Here are five such cases that made their mark on medicine. Vizzoni v. Mulford-Dera, 2019 In this case, the Superior Court of New Jersey Appellate Division upheld a trial court [decision](https://www.ama-assn.org/practice-management/sustainability/new-jersey-court-weighs-whether-non-patient-can-sue-physician) to dismiss a malpractice lawsuit after the family of a New Jersey woman who was killed during a car-bicycle accident sued the driver’s psychiatrist for medical negligence. The psychiatrist had been treating the driver, Barbara Mulford-Dera, for psychological conditions, and when Mulford-Dera struck and killed the cyclist, she had been taking a prescription medication that she allegedly did not know made it dangerous to drive. The bicyclist’s family maintained that the psychiatrist should have disclosed the potentially harmful effects of driving while under the influence of the prescribed psychotropic medication. But the trial court dismissed the case, ruling that it was not medical negligence. In an amicus brief, the American Medical Association warned that expanding physician legal obligations to the general public would have profound negative implications for medical professionals. State of Washington v. US Department of Health and Human Services, 2019 In this case, a federal judge in Washington issued a nationwide injunction blocking a series of proposed abortion restrictions. The restrictions, issued by the Trump administration, would have barred federally funded family planning facilities from advising or assisting patients seeking an abortion. Facilities backed by federal funding under the Title X program, including Planned Parenthood, were already prohibited from using those funds to perform abortions, but under this so-called “gag rule,” they would no longer be able to say or do anything to assist patients who were seeking an abortion, including referring them for abortion procedures. The rule was promulgated in March 2019 by the Department of Health and Human Services, and blocked by a federal judge the following month. In support of the injunction against the proposed plan, Washington state Attorney General Bob Ferguson [said](https://www.governor.wa.gov/news-media/updated-statements-inslee-and-ag-ferguson-regarding-judges-national-injunction-ruling) that it “ensures that clinics across the nation can remain open and continue to provide quality, unbiased healthcare to women.” National Federation of Independent Business v. Sebelius, 2012 In a Supreme Court ruling, a key provision in the Affordable Care Act (ACA), passed by Congress in 2010, was upheld. The ACA, created during the Obama administration, contained an individual mandate that required all Americans to buy health insurance or pay a tax penalty. It also required states to expand their Medicaid programs or risk losing federal funding. The court upheld the individual mandate on American citizens but rejected the provision to withhold federal funding from states that didn’t expand Medicaid, ruling that state participation in the program would be voluntary. “The Affordable Care Act’s requirement that certain individuals pay a financial penalty for not obtaining health insurance may reasonably be characterized as a tax,” Chief Justice John Roberts wrote in the [ruling](https://www.law.cornell.edu/supremecourt/text/11-393#writing-11-393_OPINION_3). “Because the Constitution permits such a tax, it is not our role to forbid it, or to pass upon its wisdom or fairness.”

#### The Courts are key --- reaffirming judicial supremacy is necessary to check back on majoritarian power and preserve a system of checks and balances --- that prevents the collapse of democracy

Redish and Heins 16 [Martin Redish, Louis and Harriet Ancel Professor of Law and Public Policy, Northwestern University School of Law. Matthew Heins, B.A. 2009, University of Southern California; J.D. 2015, Northwestern University School of Law. “Premodern Constitutionalism.” April 15, 2016. https://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=3651&context=wmlr]

The argument Kramer and others advance is not only normatively unpersuasive, it is also logically untenable in light of the structural Constitution and the basic premises of American constitutionalism. As we explained in Part I, the traditionalist view understands the value of countermajoritarian checking as a political mechanism for enshrining skeptical optimism, which can be readily deduced from the Constitutions structural design. Our constitutionalism is thus principally concerned with facilitating democracy while promoting rule of law values and protecting minorities.296 The reality is that any argument that temporary majorities or the governmental bodies that are directly accountable to those majorities are either more capable or more suitable arbiters of constitutional meaning ignores the careful framework for promoting these values that was etched into our supreme law at the constitutional convention. Our proclaimed unflagging commitment to due process of law, the existence of a supreme document ratified by supermajoritarian movement and subject to formal alteration only through a supermajoritarian process, and our provision of a politically insulated judiciary are all brightly flashing signals that our system understands the importance of speed bumps to slow majorities down. Popular constitutionalism seems to forget or intentionally ignore all of this. 297 Mark Tushnets case against judicial supremacy directly takes on Larry Alexanders and Frederick Schauers defense of judicial review.298 Alexander and Schauer assert that without judicial supremacy we would have a system of interpretive anarchy on our hands.299 The role of the Supreme Court, say Alexander and Schauer, is to provide a single authoritative interpreter to which others must defer, to serve the settlement function of the law. 300 Tushnet responds that when it declares that Congress has overstepped its bounds, the Court justifies its behavior using the selfinterestedness of the Congress: Congress is self-interested when it defines the scope of its own power. Members of Congress have an interest in maximizing their own power by expanding their sphere of power and responsibilities. Any decision [Congress] make[s], no matter how fully deliberated, will be shaped, and perhaps distorted, by this self-interest. 301 But this is an objection equally available to those who would question the Courts version of judicial supremacy, because the judiciary is just as apt to act self-interestedly and expand its own power.302 This position runs directly contrary to the basic principles underlying the structural Constitution. Tushnets argument essentially ignores the fact that the judiciary was built to be (1) limited in active power, and (2) countermajoritarian, staffed by insulated judges with salary and tenure protections. With the exception of issues surrounding its own powers, the judiciary is uniquely positioned to serve as the neutral adjudicator that can settle disputes as to the boundaries between executive and legislative, as well as federal and state branches. More importantly, if the judiciary were not tasked with settling the boundaries of majoritarian power, there would be no countermajoritarian check at all, and the Constitution would essentially be meaningless. And even as to its own power, the Courts authorityunlike that of Congress or the Presidentis confined to a passive role, awaiting cases to adjudicate.303 It therefore makes sense to give the Court final say as to its own constitutional power in order to protect its countermajoritarian role.304 Under a regime of judicial supremacy, the judiciary is no more capable of aggrandizement than is Congress. Professor Tushnet looks to City of Boerne v. Flores to show how the Court gives deference to Congress and assumes laws are constitutional because Congress has a duty to support the Constitution, but the Court does not give deference to congressional redefinitions of its own power because Congress is self-interested.305 But, he argues, the Court is no less self-interested because every institution with both power and the ability to aggrandize it will seek to expand or enhance that power.306 Both of Professor Tushnets proof points are flawed. The Court is no more empowered to engage in self-aggrandizement than is Congress, considering that Congress is arguably capable of simply stripping the federal courts of jurisdiction (within constitutional limits) whenever it chooses.307 Why would it be, under Tushnets theory, that the Framers would devise a constitutional system in which the Congress could be trusted to determine the scope of its own power, disregarding judicial pronouncements of the limits of that power, and then could strip the courts of jurisdiction to hear any challenges to such self-aggrandizement? Tushnet has effectively written Article III out of the Constitution. And although he focuses his attention on the fact that the Court is no more a single authoritative interpreterthan is Congressor maybe even less singular, because each individual voice is so much more meaningful on the Court308Tushnet forgets that Congress represents hundreds of millions of people and is, at some level, subject to their momentary preferences. What makes the Court uniquely capable of serving as the final voice of constitutional interpretationthe single authoritative interpreter that Alexander and Schauer describe and that the Framers envisioned is that it is insulated from such political pressure.309 Arguing that judicial supremacy distorts legislation, Professor Tushnet suggests that without it, Congress would act more responsibly in interpreting and abiding by the Constitution.310 For example, in the context of flag burning, he contends that judicial supremacy problematically prevented Congress from doing what its members and the people wantednamely, passing an effective law against the burning of the American flag.311 But that is exactly the point. Presumably by the exact same reasoning, it could have been argued that during the McCarthy era, the judiciary should not have been allowed to prevent the majority from doing what it wanted to do namely, suppress left-wing dissenters. The entire purpose of our structural Constitution is to embed Founding-era American skeptical optimism and force the majority, if it wishes to circumvent those fundamental truths, to garner enough supermajoritarian support to change them. If the American people are so concerned with flag burning, it is a good thing to require them to amend the Constitution formally, by means of the prescribed supermajoritarian process312to render constitutional those state or federal laws that ban it. If burning the flag is a method of expression, and laws forbidding it are contrary to the First Amendment because of their communicative impact, the people may amend the Constitution to declare thatflag-burning laws are an exception to the Amendments general coverage.313 Tushnet believes that lawmakers may apply their own conception of the Constitution if they are conscientious and if their interpretation is reasonable, 314 but this begs the question: Who is to decide whether a lawmaker has conscientiously considered and reasonably interpreted the Constitution? The lawmaker himself? Our constitutional democracy cannot survive such constant, momentary, self-interested reinterpretation. Tushnet says it is wrong to assume that members of Congress are inherently incapable of interpreting the Constitution.315 But the traditionalist view of American constitutionalism in no way stands for the position that Congress is incapable of properly exercising interpretive authority. To the contrary, we both hope and assume that Congress is doing just that in deciding whether to enact legislation. The Constitution does not in any way prohibit the majoritarian branches from ever exercising interpretive authority; in fact, as Professor Paulsen discusses with great alacrity, each and every politically accountable member of the federal government takes an oath to support the Constitution.316 Congress might be undereducated about the Constitution, and it might be that Congress would improve without the judiciary as a backstop, especially if given the same kind of institutional support that the executive receives in its endeavors of constitutional interpretation, such as the Solicitor Generals Office and the Department of Justices Office of Legal Counsel. 317 But this misses the point entirely. The problem is not that Congress is bad at constitutional interpretationit is that because of its inherently majoritarian nature, Congress is structurally incapable of effectively policing majoritarian threats to the values and dictates embodied in the countermajoritarian Constitution. This is especially true when Congress itself creates those threats. Thus, our structural Constitution does not envision Congress as the final interpreter, and for good reason. The peoples elected representatives exist to advance the current and future interests of their constituents; the courts exist to ensure that those current and future legislative and policy choices adhere to foundational principles embodied in the nations countermajoritarian supreme law.

#### Democratic backsliding causes extinction.

Kendall-Taylor 16 [Andrea; Deputy national intelligence officer for Russia and Eurasia at the National Intelligence Council, Senior associate in the Human Rights Initiative at the Center for Strategic and International Studies in Washington; “How Democracy’s Decline Would Undermine the International Order,” CSIS; 7/15/16; <https://www.csis.org/analysis/how-democracy%E2%80%99s-decline-would-undermine-international-order>/] Justin

It is rare that policymakers, analysts, and academics agree. But there is an emerging consensus in the world of foreign policy: threats to the stability of the current international order are rising. The norms, values, laws, and institutions that have undergirded the international system and governed relationships between nations are being gradually dismantled. The most discussed sources of this pressure are [the ascent of China](http://nationalinterest.org/feature/how-china-sees-world-order-15846) and other non-Western countries, Russia’s assertive foreign policy, and the diffusion of power from traditional nation-states to nonstate actors, such as nongovernmental organizations, multinational corporations, and technology-empowered individuals. Largely missing from these discussions, however, is the [specter of widespread democratic decline](http://www.journalofdemocracy.org/article/facing-democratic-recession). Rising challenges to democratic governance across the globe are a major strain on the international system, but they receive [far less attention](http://www.iiss.org/en/publications/survival/sections/2016-5e13/survival--global-politics-and-strategy-april-may-2016-eb2d/58-2-03-boyle-6dbd) in discussions of the shifting world order.

In the 70 years since the end of World War II, the United States has fostered a global order dominated by states that are liberal, capitalist, and democratic. The United States has promoted the spread of democracy to strengthen global norms and rules that constitute the foundation of our current international system. However, despite the steady rise of democracy since the end of the Cold War, over the last 10 years we have seen dramatic reversals in respect for democratic principles across the globe. [A 2015 Freedom House report](https://freedomhouse.org/sites/default/files/01152015_FIW_2015_final.pdf) stated that the “acceptance of democracy as the world’s dominant form of government—and of an international system built on democratic ideals—is under greater threat than at any point in the last 25 years.”

Although the number of democracies in the world is at an all-time high, there are a number of [key trends](file:///C:\Users\PMeylan\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\5V2CJVRN\160715_KendallTaylor_DemocracysDecline_Commentary.docx#http://www.journalofdemocracy.org/article/democracy-decline) that are working to undermine democracy. The rollback of democracy in a few influential states or even in a number of less consequential ones would almost certainly accelerate meaningful changes in today’s global order.

Democratic decline would weaken U.S. partnerships and erode an important foundation for U.S. cooperation abroad. [Research demonstrates](file:///C:\Users\PMeylan\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\5V2CJVRN\160715_KendallTaylor_DemocracysDecline_Commentary.docx#http://cmp.sagepub.com/content/18/1/49.abstract) that domestic politics are a key determinant of the international behavior of states. In particular, democracies are more likely to form alliances and cooperate more fully with other democracies than with autocracies. Similarly, authoritarian countries have established mechanisms for cooperation and sharing of “worst practices.” An increase in authoritarian countries, then, would provide a broader platform for coordination that could enable these countries to overcome their divergent histories, values, and interests—factors that are frequently cited as obstacles to the formation of a cohesive challenge to the U.S.-led international system.

Recent examples support the empirical data. Democratic backsliding in Hungary and the hardening of Egypt’s autocracy under Abdel Fattah el-Sisi have led to enhanced relations between these countries and Russia. Likewise, democratic decline in Bangladesh has led Sheikh Hasina Wazed and her ruling Awami League to seek closer relations with China and Russia, in part to mitigate Western pressure and bolster the regime’s domestic standing.

Although none of these burgeoning relationships has developed into a highly unified partnership, democratic backsliding in these countries has provided a basis for cooperation where it did not previously exist. And while the United States certainly finds common cause with authoritarian partners on specific issues, the depth and reliability of such cooperation is limited. Consequently, further democratic decline could seriously compromise the United States’ ability to form the kinds of deep partnerships that will be required to confront today’s increasingly complex challenges. Global issues such as climate change, migration, and violent extremism demand the coordination and cooperation that democratic backsliding would put in peril. Put simply, the United States is a less effective and influential actor if it loses its ability to rely on its partnerships with other democratic nations.

A slide toward authoritarianism could also challenge the current global order by diluting U.S. influence in critical international institutions, including the [United Nations](https://www.washingtonpost.com/opinions/christopher-walker-authoritarian-regimes-are-changing-how-the-world-defines-democracy/2014/06/12/d1328e3a-f0ee-11e3-bf76-447a5df6411f_story.html) , the World Bank, and the International Monetary Fund (IMF). Democratic decline would weaken Western efforts within these institutions to advance issues such as Internet freedom and the responsibility to protect. In the case of Internet governance, for example, Western democracies support an open, largely private, global Internet. Autocracies, in contrast, promote state control over the Internet, including laws and other mechanisms that facilitate their ability to censor and persecute dissidents. Already many autocracies, including Belarus, China, Iran, and Zimbabwe, have coalesced in the “Likeminded Group of Developing Countries” within the United Nations to advocate their interests.

Within the IMF and World Bank, autocracies—along with other developing nations—seek to water down conditionality or the reforms that lenders require in exchange for financial support. If successful, diminished conditionality would enfeeble an important incentive for governance reforms. In a more extreme scenario, the rising influence of autocracies could enable these countries to bypass the IMF and World Bank all together. For example, the Chinese-created Asian Infrastructure and Investment Bank and the BRICS Bank—which includes Russia, China, and an increasingly authoritarian South Africa—provide countries with the potential to bypass existing global financial institutions when it suits their interests. Authoritarian-led alternatives pose the risk that global economic governance will become [fragmented and less effective](http://www.tandfonline.com/doi/abs/10.1080/00396338.2016.1161899?journalCode=tsur20#.V2H3MRbXgdI).

Violence and instability would also likely increase if more democracies give way to autocracy. [International relations literature](https://www.foreignaffairs.com/articles/china/1995-05-01/democratization-and-war) tells us that democracies are less likely to fight wars against other democracies, suggesting that interstate wars would rise as the number of democracies declines. Moreover, within countries that are already autocratic, additional movement away from democracy, or an “authoritarian hardening,” would increase global instability. Highly repressive autocracies are the most likely to experience state failure, as was the case in the Central African Republic, Libya, Somalia, Syria, and Yemen. In this way, democratic decline would significantly strain the international order because rising levels of instability would exceed the West’s ability to respond to the tremendous costs of peacekeeping, humanitarian assistance, and refugee flows.

Finally, widespread democratic decline would contribute to rising anti-U.S. sentiment that could fuel a global order that is increasingly antagonistic to the United States and its values. Most autocracies are highly suspicious of U.S. intentions and view the creation of an external enemy as an effective means for boosting their own public support. Russian president Vladimir Putin, Venezuelan president Nicolas Maduro, and Bolivian president Evo Morales regularly accuse the United States of fomenting instability and supporting regime change. This vilification of the United States is a convenient way of distracting their publics from regime shortcomings and fostering public support for strongman tactics.

Since 9/11, and particularly in the wake of the Arab Spring, Western enthusiasm for democracy support has waned. Rising levels of instability, including in Ukraine and the Middle East, fragile governance in Afghanistan and Iraq, and sustained threats from terrorist groups such as ISIL have increased Western focus on security and stability. U.S. preoccupation with intelligence sharing, basing and overflight rights, along with the perception that autocracy equates with stability, are trumping democracy and human rights considerations.

While rising levels of global instability explain part of Washington’s shift from an historical commitment to democracy, the nature of the policy process itself is a less appreciated factor. Policy discussions tend to occur on a country-by-country basis—leading to choices that weigh the costs and benefits of democracy support within the confines of a single country. From this perspective, the benefits of counterterrorism cooperation or access to natural resources are regularly judged to outweigh the perceived costs of supporting human rights. A serious problem arises, however, when this process is replicated across countries. The bilateral focus rarely incorporates the risks to the U.S.-led global order that arise from widespread democratic decline across multiple countries.

Many of the threats to the current global order, such as China’s rise or the diffusion of power, are driven by factors that the United States and West more generally have little leverage to influence or control. Democracy, however, is an area where Western actions can affect outcomes. Factoring in the risks that arise from a global democratic decline into policy discussions is a vital step to building a comprehensive approach to democracy support. Bringing this perspective to the table may not lead to dramatic shifts in foreign policy, but it would ensure that we are having the right conversation.

#### Aff is congress

#### 1] Spec – lack of it in the 1ac means default to 1nc NM ev. Anything else lets the 1ar shift the direction of the aff based on the 1nc strategy which crowds out the only core generics on the topic. Normal means doesn’t solve bc they will contest it in the 1ar and change their strategy based on the 1nc. No infinite regress because we only want you to spec one thing. CX doesn’t check because we construct the 1nc pre-round and debaters are intentionally shifty to avoid deep clash.

#### 2] Congress for this topic.

Orelli and Speights 5/29 [Dr. Orelli is a Senior Biotech Specialist. He has written about biotech, pharmaceutical, and medical device companies for The Motley Fool since 2007. May 29, 2021. “Will Patent Waivers Hurt COVID-19 Vaccine Companies?” [Will Patent Waivers Hurt COVID-19 Vaccine Companies? | The Motley Fool](https://www.fool.com/investing/2021/05/29/will-patent-waivers-hurt-covid-19-vaccine-companie/) Accessed 9/3 //gord0]

**Brian Orelli**: Last week, the Biden administration endorsed a proposal to waive COVID-19 vaccine patent rights. How big of a deal is this for the current vaccine makers like Moderna, BioNTech, Pfizer, and Johnson & Johnson?

**Keith Speights**: I really don't think that this is as big of a deal as some people are making it out to be. Certainly, not as big of a deal as the declines for the stocks showed last week.

I noticed that Moderna's CEO said publicly that he didn't lose a minute of sleep over this news. I think he's right; he shouldn't have lost any sleep. His reasoning was that there are other companies that, if they had access to the technology, they're not going to have the expertise to make the messenger RNA vaccines that Moderna makes. His thought was, "Look, even if this happens, we're not going to be threatened all that much." I suspect that he is right.

Now, Pfizer's CEO, Albert Bourla, did express some concerns. He wrote in a statement that this proposed intellectual-property-rights waiver could actually create more problems than it would solve. Bourla noted that infrastructure really isn't the bottleneck for Pfizer; it is the availability of raw materials. He thinks that this IP waiver would kick off a global scramble for those raw materials. The companies that don't have much expertise developing these vaccines could potentially disrupt the supply chain for companies like Pfizer that do have the expertise.

It wouldn't surprise me if that scenario that Bourla described might would happen to some extent. However, I would think that companies like Pfizer and Moderna would likely be able to pay a lot more for these raw materials and secure the suppliers they need and put the other companies that are trying to make these vaccines on their own at a severe disadvantage. But if that happened, I would think that Pfizer, Moderna would probably have to hike their prices to countries like the U.S. that could pay up.

Bourla also expressed some concerns that this move could provide disincentives to companies to take risks in the future. My thought on that, though, if it's only a temporary thing, it probably wouldn't be too much of an issue. But I think the big story [laughs] here is that this is probably all much ado about nothing, because Germany has already come out and said they are opposed to granting this temporary waiver and they are a member of the World Trade Organization, and from what I understand, Brian, they have veto power like other WTO members do. If Germany vetoes this, then all of this talk is a waste of time. [laughs] So I don't think this is going to be a big deal. I don't think it's going to go through, but even if it does, I just don't think this is a huge deal for Pfizer and Moderna and some of the other big vaccine makers.

**Orelli**: If it does go through, do you think it's a slippery slope? This is a pandemic; that makes sense. But then when you start doing it for cancer drugs that are really expensive or the insulin because people need it to live? That sort of thing.

**Speights**: I think it could be. I don't think it will be. The Biden administration is caving a little bit here, I think, to some pressure from within the Democratic Party. I don't think they would be -- I'm thinking any presidential administration in the U.S. -- wouldn't be in favor of just nearly [laughs] willy-nilly taking away patent rights. I think they realize that would undermine the foundation of our whole structure of drug development and that it would cause a lot more problems than it would solve. Maybe I'm being too optimistic there, Brian. I don't know about what you think, but I just don't think that's going to happen.

**Orelli**: Yeah. I guess it just depends on the state of the Congress and who's the president. I think right now, we're so divided that I don't think anything will get through Congress in its current state and probably in its future state. I think you're right, but I do worry about setting up a precedent. Although I think we've already had this one. They waved the patent rights on HIV drugs, and that didn't cause a major storm of inactivating patents over the last 20 years or however long its been since they did it. I think we're probably OK, but I just wanted to bring that up as a point.

**Speights**: Yeah. Personally, I don't think it's a good move. I think it's better to respect all intellectual-property rights and come up with a better solution. I do agree that more vaccines need to be made available to Third World countries and developing nations. I think there's probably a better way.

**Orelli**: Yeah. I think they're just letting the companies ramp up their production. Moderna is looking at 3 billion doses next year. I think that if we just let them go on [laughs] their own and maybe even support them financially, I think that should be sufficient to get us where we need to be.

### 1NC – CP

#### States should add more stringent requirements for filing secondary patents for medicines as outlined by 1NC Newsome

#### Requirements:

* Utility requirement through increased efficacy
* Proven improvement
* Medicinal mechanism

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.

#### Solves innovation

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

### 1NC – DA

#### Infrastructure passes now but political capital is key

News West 9/8 [News West. September 8, 2021. “Biden’s bipartisan bet on infrastructure has paid off so far” <https://newswest.org/bidens-bipartisan-bet-on-infrastructure-has-paid-off-so-far/> Accessed 9/13 //gord0]

Senate Minority Leader Mitch McConnell has said he is “100%” focused on stopping President Biden’s agenda — and yet he voted with every Senate Democrat last week to set the stage for passing a bipartisan infrastructure bill that would be a major political win for the White House.

He wasn’t alone. Sixteen other Republicans opted to advance the legislation — in the face of multiple missives from former President Trump urging them to block it.

At a moment of such intense partisanship, this momentary alignment of incentives for Democrats and Republicans, set to vote in the coming days to pass the approximately $1-trillion package out of the Senate, is the Washington equivalent of a total eclipse. However rare and fleeting, Republicans and Democrats believe they are serving their own self-interests, not just the president’s, in voting to pass a bipartisan bill to improve roads, bridges, rail lines, water pipes and broadband networks.

“Every incumbent benefits from the sense that the Congress can figure out how to get important things done,” said Sen. Roy Blunt (R-Mo.).

Unsurprisingly, lawmakers don’t expect the conviviality to last long.

Upon passing the bipartisan plan as soon as this weekend, Democrats hope to soon approve the framework for a second bill, a sweeping Democratic proposal that includes [massive subsidies and tax breaks for working families](https://www.latimes.com/politics/story/2021-04-28/biden-families-plan-taxes-rich-to-cover-child-care-job-leave-community-college-and-more), free preschool and community college, a large expansion of Medicare and other tax cuts. Knowing no Republicans will support that measure, Democrats plan to utilize a process known as reconciliation, which requires just 50 votes for passage.

After Trump failed to achieve infrastructure legislation — his repeated efforts to promote “Infrastructure Week” became a running Washington joke — Biden has sought to leverage his 36 years of experience in the Senate to pursue a [domestic program modeled after President Franklin Roosevelt’s New Deal](https://www.latimes.com/politics/story/2021-03-10/bidens-early-win-on-covid-relief-could-be-hard-to-repeat-or-he-could-be-fdr).

Taking office amid the COVID-19 pandemic, Biden and Democrats brushed aside Republican opposition in March to enact a $1.9-trillion relief bill. But the decision to pivot to infrastructure, according to multiple administration officials, was based on a view that legislation focused on economic recovery was the logical next step and provided Biden an opportunity to notch a bipartisan achievement.

“The president always felt like this is a bill that’s going to get Republican support because these are issues that have always been bipartisan,” said Anita Dunn, counselor to the president, in an interview. “We haven’t had a major infrastructure bill in this country for a long time, and there’s desperate need for it.”

President Obama, who provoked strong reactions from the GOP base, exhausted precious political capital in his first two years in office on a more ideological push for healthcare reform. Conversely, [Republicans have struggled to negatively define Biden](https://www.latimes.com/politics/story/2021-02-05/while-biden-pushes-crisis-response-republicans-go-to-war-with-themselves), and his prioritization of infrastructure legislation has maintained broad public support and generated little political backlash.

“It’s not like we’re asking people to vote for unpopular things,” Dunn said. “We’re asking them to vote for popular things.”

Seven in 10 Americans back the bipartisan infrastructure proposal, according to a Monmouth University [poll](https://www.monmouth.edu/polling-institute/reports/monmouthpoll_us_072921/) that the White House cited in a memo to lawmakers this week. The initiative also has the backing of the U.S. Chamber of Commerce and other trade groups, as well as the country’s largest labor unions.

With both parties looking ahead at the 2022 midterm election that will decide control of Congress, several Republicans have calculated there’s more risk in outright obstinacy than occasionally meeting the president in the middle.

“If you’re a Republican, you want to prove that you’re not just here to completely block and stop the entire agenda,” said Sen. John Thune of South Dakota, the No. 2 Republican in the Senate. “It’d be good maybe for the administration and they probably need a win right about now, but I also think that there are benefits politically to members on both sides.”

Biden’s push for bipartisan legislation has required persistence, flexibility and legislative acrobatics. After talks with Republicans faltered in early June, Biden encouraged his team to engage with a bipartisan group of senators drawing up their own infrastructure plan. After [agreeing to a basic framework](https://www.latimes.com/politics/story/2021-06-24/infrastructure-deal-bipartisan-tentative-congress), Biden nearly torpedoed the effort by saying he wouldn’t sign it until Democrats passed their own companion bill — a likely $3.5-trillion package through the budget reconciliation process.

Though [Biden quickly walked back that comment](https://www.latimes.com/world-nation/story/2021-06-27/bipartisan-infrastructure-deal-back-on-track-after-walk-back), his blunt assertion underlined his pursuit of a two-track approach that has proven — so far— to be politically shrewd.

The two bills, in theory, placate both ends of the president’s party: moderates craving a return to bipartisan deal-making and progressives eager to enact a broader agenda — giving Democrats, as some Republicans have argued, a chance to have it both ways.

“If you can get major legislation through with support from both parties, in Washington right now, that is a major accomplishment,” said Mike DuHaime, a GOP strategist in New Jersey. “He’s giving cover to a lot of Democrats in swing districts who need it.And it does give him freedom to go in a more partisan direction on other things.”

But the bifurcated approach also benefits Republicans. By backing the bipartisan bill, they can showcase a willingness to work with a Democratic administration to advance shared goals, while vehemently opposing the Democrats’ second bill, a release valve for the partisan steam that animates the party’s base.

“For Republicans, it’s a two-fer,” said Whit Ayres, a GOP pollster. “There’s lots to like in both positions.”

Sen. Kevin Cramer (R-N.D.), who has supported the bipartisan bill while opposing the Democrats’ reconciliation measure, is OK giving the president a bipartisan “win,” believing GOP lawmakers will benefit from delivering their voters long-needed improvements and projects.

“Not every transaction requires a winner and a loser,” Cramer said. “Some transactions can have winners on both sides. I think infrastructure along with national defense are the policy issues that provide opportunities for us to do the right thing.”

Republicans also feel confident that any bipartisan credit Biden receives from the deal will come crashing down when Democrats turn to the partisan proposal.

#### The plan decks PC that could be used on infrastructure – tradeoffs and negotiations

Bhadrakumar 5/11 [M.K. Bhadrakumar is a former Indian diplomat*.* May 11, 2021. “[Why Biden’s Vaccine IP Waiver is Political Theatre](https://www.counterpunch.org/2021/05/11/why-bidens-vaccine-ip-waiver-is-political-theatre/)” <https://www.counterpunch.org/2021/05/11/why-bidens-vaccine-ip-waiver-is-political-theatre/> Accessed 8/27 //gord0]

India’s Ministry of External Affairs has [welcomed](https://www.mea.gov.in/press-releases.htm?dtl/33848/Statement_on_the_US_support_for_TRIPS_Waiver) the statement of the US government of 5th May announcing their support for a relaxation in the norms of the agreement on TRIPS, to ensure quick and affordable access to vaccines and medicines for developing countries. Delhi is “hopeful that with a consensus based approach, the waiver can be approved quickly at the WTO.” But is the optimism warranted? The [US statement](https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver) itself is cautiously worded and is non-committal. It only says, “We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The Biden administration’s emphasis continues to be on “our vaccine supply for the American people.” It is an America First strategy. President Biden has plans to at least partially vaccinate 70% of adults by July 4 so that herd immunity develops that will help the level of new infections to drop. Biden’s decision on the TRIPS waiver can only be seen as a political decision. A Reuters report says citing informed sources, “Wednesday’s decision allows Washington to be responsive to the demands of the (American) left and developing countries, while using WTO negotiations to narrow the scope of the waiver. Since the negotiations will take time, the decision also buys time to boost vaccine supplies through more conventional means.” In effect, the Biden Administration is juggling several balls in the air. On the one hand, the progressive left in the US politics, including Sen. Bernie Sanders and Rep. Alexandria Ocasio-Cortez in the Democratic Party, has been demanding TRIPS waiver for Covid vaccines; equally, developing countries, supported by the WHO and the UN, are also demanding the waiver; India, a key Indo-Pacific ally of the US, was the initiator of the proposal on TRIPS waiver back in December; and, in principle, Biden Administration is committed to “multilateralism.” On the other hand, Biden whose political life of half a century was largely spent in the US Congress, is well aware of the awesome clout of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already [gone on the offensive](https://www.newsweek.com/waiving-intellectual-property-protection-what-could-go-wrong-opinion-1589273) blasting Biden’s announcement saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Sen. Richard Burr, the top Republican on the US Senate Health Committee, has denounced Biden’s decision: “Intellectual property protections are part of the reason we have these life-saving products; stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee Chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather spend his political capital on getting the necessary legislation through the Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO dragging on for months, if not years, without reaching anywhere. The US support for the waiver could even be a tactic to convince pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to quickly boost global production. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones, such as India and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be huge opposition to the TRIPS waiver from the US’ European allies as well. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### Bill key to prevent infrastructure disaster from Grid Collapse

PPG, 3/4/2021 (MAR 4, 2021 9:00 PM, Pittsburgh Post-Gazette Editorial Board. Invest in infrastructure. March 4, 2021. <https://www.post-gazette.com/opinion/editorials/2021/03/05/Invest-in-infrastructure/stories/202102270028>, recut by JMP)

Now is the time for a reckoning, a realization: While it’s important to study the past to avoid repeating the same mistakes, the country must also look to its future and see the obvious — that America’s infrastructure as a whole needs some serious upkeep.

Democrats and Republicans alike have flirted with the idea of a sweeping infrastructure bill in recent years, and President Joe Biden’s team is working to outline such legislation. These efforts should proceed swiftly — now is the time for Congress to invest in infrastructure, not only to help prevent crises, but also to jump-start an economy mired in the coronavirus pandemic.

Despite being one of the richest countries in the world, the U.S. seems constantly to hover on the edge of disaster, with news of natural forces smashing through power grids and levies and fire prevention strategies on a yearly or monthly basis. Texas is only the most recent state to have been pushed over the edge.

The American Society of Civil Engineers just this week gave America’s infrastructure an overall grade of C-minus in its quadrennial report card. The last grade was D-plus and that report cited decades of underfunding and unheeded recommendations. C-minus is an improvement but deserves not just federal attention but actual intervention. The report notes “we are heading in the right direction, but a lot of work remains.”

There is opportunity in the recent economic and environmental devastation that grabs headlines and breaks hearts. In the aftermath of the Great Depression, the government put millions to work improving parks and building roads and bridges and airports. President Dwight Eisenhower’s interstate highway system remains the life veins of interstate travel.

A new and vigorous infrastructure package for America would fix what needs to be fixed and offer the promise of an economic boon.

The purpose of the federal government is to address the needs of American society in a way that can’t be tackled by states in a piecemeal fashion. What has happened in recent days within The Lone Star State demonstrates keenly that this is the time — actually past the time — that our federal leaders must shore up the foundations of our federation. Congress should act swiftly to lead states in reversing the entropy chewing away at America’s foundations. Until this happens, society stands on shifting sands.

#### Grid collapse causes extinction.

Greene ’19 [Sherrell R.; Nuclear Engineering M.S. degrees from the University of Tennessee, recognized subject matter expert in nuclear reactor safety, nuclear fuel cycle technologies, and advanced reactor concept development, worked at the Oak Ridge National Laboratory (ORNL) for over three decades, as Director of Research Reactor Development Programs and Director of Nuclear Technology Programs; “Enhancing Electric Grid, Critical Infrastructure, and Societal Resilience with Resilient Nuclear Power Plants (rNPPs),” Nuclear Technology 205(3), <https://ans.tandfonline.com/doi/pdf/10.1080/00295450.2018.1505357?needAccess=true> recut gord0]

There are a variety of events that could deal ~~crippling~~ blows to a nation’s Grid, Critical Infrastructure, and social fabric. The types of catastrophes under consideration here are “very bad day” scenarios that might result from severe GMDs induced by solar CMEs, HEMP attacks, cyber attacks, etc.5

As briefly discussed in Sec. III.C, the probability of a GMD of the magnitude of the 1859 Carrington Event is now believed to be on the order of 1%/year. The Earth narrowly missed (by only several days) intercepting a CME stream in July 2012 that would have created a GMD equal to or larger than the Carrington Event.41 Lloyd’s, in its 2013 report, “Solar Storm Risk to the North American Electric Grid,” 42 stated the following: “A Carrington-level, extreme geomagnetic storm is almost inevitable in the future…The total U.S. population at risk of extended power outage from a Carrington-level storm is between 20-40 million, with durations of 16 days to 1-2 years…The total economic cost for such a scenario is estimated at $0.6-2.6 trillion USD.” Analyses conducted subsequent to the Lloyd’s assessment indicated the geographical area impacted by the CME would be larger than that estimated in Lloyd’s analysis (extending farther northward along the New England coast of the United States and in the state of Minnesota),43 and that the actual consequences of such an event could actually be greater than estimated by Lloyd’s.

Based on “Report of the Commission to Assess the Threat to the United States from Electromagnetic Pulse (EMP) Attack: Critical National Infrastructures” to Congress in 2008 (Ref. 39), a HEMP attack over the Central U.S. could impact virtually the entire North American continent. The consequences of such an event are difficult to quantify with confidence. Experts affiliated with the aforementioned Commission and others familiar with the details of the Commission’s work have stated in Congressional testimony that such an event could “kill up to 90 percent of the national population through starvation, disease, and societal collapse.” 44,45 Most of these consequences are either direct or indirect impacts of the predicted collapse of virtually the entire U.S. Critical Infrastructure system in the wake of the attack.

Last, recent analyses by both the U.S. Department of Energy46 and the U.S. National Academies of Sciences, Engineering, and Medicine47 have concluded that cyber threats to the U.S. Grid from both state-level and substatelevel entities are likely to grow in number and sophistication in the coming years, posing a growing threat to the U.S. Grid.

These three “very bad day” scenarios are not creations of overzealous science fiction writers. A variety of mitigating actions to reduce both the vulnerability and the consequences of these events has been identified, and some are being implemented. However, the fact remains that events such as those described here have the potential to change life as we know it in the United States and other developed nations in the 21st century, whether the events occur individually, or simultaneously, and with or without coordinated physical attacks on Critical Infrastructure assets.

## Case

### NC – AT: Evergreening

#### 1] No impact to PFAD—our ev says investment writ large in biotech R&D is high now.

#### **2] Evergreening is a myth—multiple legal barriers prevent unjustified extensions of patents.**

Lietzan ‘20 (Erika Lietzan; William H. Pittman Professor of Law and Timothy J. Heinsz Professor of Law at the University of Missouri School of Law; Fall 2020; "The Evergreening Myth"; https://www.cato.org/regulation/fall-2020/evergreening-myth, Cato Institute, accessed 9-6-2021; JPark)

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.

#### 3] The purpose of evergreening is to make money—medical advances are direct effects of the money big pharma makes. Proves secondary patents kill innovation

Collier 13

Roger Collier (consultant specializing in health care policy issues, CEO of national healthcare consulting firm, Principal-in-Charge off KPMG’s national health and welfare consulting practice); “Drug patents: the evergreening problem”; CMAJ Vol. 185, Issue 9; June 11, 2013; <https://www.cmaj.ca/content/185/9/E385/tab-e-letters>; EMJ

“Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company’s economic advantage,” says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. “The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.” Evergreening has been a hot topic of late because of the recent ruling by India’s Supreme Court to refuse to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec (imatinib mesylate), or Glivec, as it’s known in some countries. Novartis claims the drug is more easily absorbed into the blood and, considering it is used to fight leukemia, that is enough of an improvement to warrant patent protection. But India’s trade and industry minister, Anand Sharma, has defended the decision, and was quoted by Agence France-Presse as saying it was “absolutely justified under the law” and that India’s patent law “does not accept evergreening.”

4] **Alt causes -- evergreening doesn't extend patent for the original product**

**Holman 20** [Chris Holman, Senior Fellow for Life Sciences & Senior Scholar @ Center for Intellectual Property x Innovation Policy, Professor at the University of Missouri-Kansas City School of Law. "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection", Geneva Network, 2-7-2020, accessed 9-5-2021, https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/] HWIC

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.

Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself.

For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

#### 5] All critiques of evergreening are wrong—it’s essential to encourage competition in the market, and improvements come in increments.

Thomas 09

John R. Thomas (Georgetown Law Center faculty, Visiting Scholar at the Congressional Research Service, inaugural Thomas Alva Edison Visiting Scholar at the U.S. Patent and Trademark Office);

Although the practice of evergreening has attracted considerable criticism, many observers believe these critiques are misplaced. Indeed, some consider the term “evergreening” to be inappropriate, and even derogatory in nature.62 They explain that the patent laws promote both original and improvement inventions, that most technological advance occurs incrementally, that improvements may be developed by competitors of the original innovator, that many improvement patents cover advances that are of considerable medical significance, and that patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. This report reviews these assertions in turn. First, these observers note that the patent system allows patents to be obtained on both original and improvement technologies. As a result, the patent law encourages the development of both kinds of inventions. They also explain that under the Patent Act, each invention must fulfill a number of requirements in order to be subject to patent protection. Among these criteria are that the invention must be novel,63 nonobvious,64 and fully disclosed in an application submitted to the USPTO.65 These statutory standards are applied neutrally to each kind of invention, whether it may be characterized as an “original” (such as a medication that has never been previously approved by the FDA) or an “improvement” (such as a new formulation of a known medication). Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas… Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.68 Observers also note that the developer of the “original” product is not always the same entity as the developer of “improvement” technologies. Sometimes competitors of the “original” patent proprietor, including generic drug companies, develop and patent the improvements.69 The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace.70

### NC – AT: Superbugs

#### Either they cant solve or no AMR.

Fikes 17 – U-T San Diego's biotechnology reporter; covered the industry since 1990, internally cites study by authors from Harvard Medical School [Bradley J., 5/11/2017, “Long before the dinosaurs, antibiotic-resistant superbugs thrived”, The San Diego Union-Tribune, <http://www.sandiegouniontribune.com/business/biotech/sd-me-antibiotic-resistance-20170511-story.html>] AMarb

There’s a good reason why antibiotic-resistant bacteria are so tough, and it has less to do with humans than previously thought, according to a new study. A class of bacteria containing particularly troublesome superbugs that today plague hospitals dates back at least 425 to 450 million years, according to a team of Massachusetts researchers. Called enterococci, these hardy bacteria have endured several mass extinctions, including the Permian catastrophe of about 252 million years ago that destroyed nearly all species, including the trilobites. They survived the extinction of non-avian dinosaurs at the end of the Cretaceous without missing a beat. Using genetic techniques to track the diversification of enterococci, the researchers found that this group dates back to the time when animals first left the water for land. Moreover, their divergence also matched the emergence of new animal species, especially after the Permian extinction. The implication for those fighting superbugs is that antibiotic resistance is part of a survival toolkit that has been baked into their DNA for hundreds of millions of years. Overcoming everything Mother Nature could throw at them, these ancient bacteria are well-equipped to handle antibiotics and other means of controlling them that humans can devise. “Enterococci are distinguished from their ancestors and appear to have been selected for, by virtue of having developed a hardened cell wall and the ability to cope with environmental stress —traits that now render them resistant to denaturing solvents, disinfectants, and intrinsically, to many antibiotics,” the study concluded. “These are exactly the traits that enable them to persist in the modern hospital environment. Thus, the emergence of enterococci as leading hospital pathogens appears to have been foreordained by events of at least 425 mya.”

#### Concede new diseases are coming but only vaccines can solve—proves impact UQ for the DA.

### NC – AT: Global Health Diplomacy

#### 1] No internal link—no reverse causal ev why global health diplomacy key to preventing escalation or why pharma coop scales up tech to prevent instability

#### 2] TRIPS is essential to modern health diplomacy

Obijiofor Aginam 10, Academic Programme Officer & Director of Studies, Institute for Sustainability and Peace, United Nations University headquarters, Tokyo, Japan; Adjunct Research Professor of Law, Carleton University, Ottawa, Canada, “HEALTH OR TRADE? A CRITIQUE OF CONTEMPORARY APPROACHES TO GLOBAL HEALTH DIPLOMACY,” https://poseidon01.ssrn.com/delivery.php?ID=149097083081123105113085099123123091104014059082060018071001088023116023118119002064117119051059021051011085110010121013091016020070011051015018011008065019104127084042076098081007102099120087031085093119071127122005124010118009001092104124120121094&EXT=pdf&INDEX=TRUE

The third limb of global health diplomacy critique reflects the complex linkages between “health and trade”18 where the modest achievements in global health diplomacy in the past decade are substantially driven not by events in the health sector but by the normative developments in the trade and economic relations of states enforced by the WTO. Although this sounds like “economic globalization triumphalism”, it is nonetheless hard to dispute the fact that it was the patent requirements for pharmaceuticals and other inventions in the WTO TRIPS Agreement that substantially catalyzed the health diplomacy on access to anti-retroviral drugs for HIV/AIDS for millions of poor HIV-positive who live mostly in developing countries. Food safety and security concerns and the hard diplomacy animated by biotechnology advances in food production, although global health issues in their own right, are catalyzed by the developments in the WTO on the SSPS Agreement, and not the subtle “diplomacy” around the WHO/FAO jointly administered Codex Alimentarius Commission standards. The migration of qualified health professionals from most of Africa to the West is now being driven in complex ways by one of the modes of service supply in the GATS Agreement.

#### 3] No uq- even if NTDs not recognized, diplomacy is HIGH NOW so there’s no uniqueness for the advantage